Mauna Kea Technologies

A Public Limited Company (Société anonyme) with share capital of €1,222,869.60
Registered office: 9 rue d'Enghien
75010 Paris, France
431 268 028 in the Paris Trade and Companies Register

# UNIVERSAL REGISTRATION DOCUMENT 2019
## Including the annual financial report

AUTORITÉ DES MARCHÉS FINANCIERS
AMF

This universal registration document was filed on August 7, 2020 with the Autorité des marchés financiers (the "**AMF**" - French Financial Markets Authority), as the competent authority with respect to Regulation (EU) 2017/1129, without prior approval in accordance with Article 9 of the said regulation.

The universal registration document may be used for the purposes of a public offer of securities or the admission of securities to trading on a regulated market if it is supplemented by a securities note and, where appropriate, a summary and any amendments to the universal registration document. The whole is approved by the AMF in accordance with Regulation (EU) 2017/1129.

Pursuant to Article 19 of Regulation (EU) 2017/1129 of June 14, 2017, the information contained in the following documents is incorporated by reference in this Universal Registration Document (the "**Universal Registration Document**" or the "**URD**"):

- for fiscal year 2018, shown in the Mauna Kea Technologies Registration Document filed with the Autorité des Marchés Financiers on July 12, 2019 under number D.19-0683: the consolidated and annual financial statements, the Statutory Auditors' reports, the Management Report, as well as key figures relating to the company;
- for fiscal year 2017, shown in the Mauna Kea Technologies Registration Document filed with the Autorité des Marchés Financiers on April 27, 2018 under number D.18-0429: the consolidated and annual financial statements, the Statutory Auditors' reports, the Management Report, as well as key figures relating to the company.

Copies of this Universal Registration Document are available free of charge from the Company at 9 rue d'Enghien, 75010 Paris, France as well in electronic format on the Company's website (https://www.maunakeatech.com/fr/) and on the AMF's website (www.amf-france.org).

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## GENERAL OBSERVATIONS

*Definitions*

In this Universal Registration Document, and unless otherwise indicated:

- the term "**Mauna Kea Technologies**" or the "**Company**" refers to Mauna Kea Technologies SA;
- the term "**Mauna Kea Technologies Inc.**" or the "**Subsidiary**" refers to the American subsidiary Mauna Kea Technologies Inc., wholly owned by Mauna Kea Technologies S.A.;
- the term "**Group**" refers to Mauna Kea Technologies SA and its subsidiary.

*Disclaimer*

This Universal Registration Document contains information relating to the Company's business and the market and industry in which it operates. This information comes from studies prepared either by internal or external sources (e.g. industry publications, specialized studies, information published by market research companies, analysts' reports, etc.). The Company believes that this information gives a true and fair view of its reference market and its competitive positioning in this market. However, this information has not been independently verified by the Company and the Company cannot guarantee that a third party using different methods to compile, analyze or calculate market data would obtain the same results.

This Universal Registration Document also includes information on the Company's objectives and development areas. Such indications are sometimes identified by the use of the future tense, the conditional tense and forward-looking terms such as "estimate", "consider", "aim", "expect", "intend", "should", "will" and "may" or other similar variants or terminology. The reader's attention is drawn to the fact that these objectives, forward-looking statements and development areas are not historical data and should not be interpreted as a guarantee that the facts and data stated will occur, that the assumptions will be verified or that the objectives will be achieved. Objectives or forward-looking statements, by their nature, may not be achieved and the information produced in this Universal Registration Document may prove to be erroneous without the Company being under any obligation to update it, subject to applicable regulations, in particular the General Regulations of the Autorité des marchés financiers (the "**AMF**"). In addition, some of these data, assumptions and estimates derive from or are based, in whole or in part, on assessments or decisions made by the Company's management bodies, directors or shareholders, which may change or be modified in the future.

Investors are asked to consider the risk factors described in this Universal Registration Document before taking their investment decision. The occurrence of some or all of these risks could have an adverse effect on the Company's business, position, financial results or objectives. In addition, other risks, not yet identified or considered insignificant by the Company, could have the same adverse effect and investors could lose all or part of their investment. In addition, the global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic is likely to impact the Company's business will depend on future developments, which cannot be predicted with certainty at the time of this document's registration.

A glossary at the end of this Universal Registration Document defines certain technical terms of reference, as well as cross-reference tables, which enable the information incorporated by reference and that which has been updated or amended, to be understood.

# SECTION 1
# 1. PERSONS RESPONSIBLE

## 1.1 Person responsible for the Universal Registration Document

Mr. Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies.

## 1.2 Attestation of the person responsible

*"Having taken all reasonable measures to this end, I declare that the information contained in this Universal Registration Document is, to my knowledge, in keeping with the facts, and leaves out nothing that might impact on its substance.*

*I attest that to my knowledge the financial statements were prepared in accordance with applicable accounting standards and fairly represent the assets, financial position and results of the Company and all entities within its scope of consolidation, and that the management report included herein, whose information is set 9.2out in the Section 9.2 "Results analysis", presents an accurate picture of the ongoing business, results and financial position of the Company and all entities within its scope of consolidation along with a description of the principal risks and uncertainties.*"

Paris, August 7, 2020

**Robert L. Gershon**
Chief Executive Officer

## 1.3 Persons responsible for the financial information

**Robert L. Gershon**
**Chief Executive Officer**
Address: 9, rue d'Enghien, 75010 Paris, France
Telephone: +33 (0)1 70 08 09 70
Fax: +33 (0)1 70 08 09 77
Email: investor-dg@maunakeatech.com

## 1.4 Expert statements and declarations of interest

N/A.

## 1.5 Third party information

N/A.

## 1.6 Statement of the competent authority relating to the approval of the document

See the cover page of this Universal Registration Document.

# SECTION 2
# 2. STATUTORY AUDITORS

## 1.1 Main statutory auditors

**Exco Socodec**
Member of the Regional Company of Auditors of Dijon
Represented by Mr. Olivier Gallezot
51 Avenue Françoise Giroud, 21000 Dijon

Date of start of first term of office: June 13, 2018
Duration of the current term of office: six financial years from June 13, 2018
Expiration date of the current term of office: at the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2023

**Ernst & Young et Autres**
Member of the Regional Company of Auditors of Versailles
Represented by Mr. Franck Sebag
1/2 Place des Saisons, 92400 Courbevoie – Paris-La Défense 1, France

Date of start of first term of office: May 25, 2011
Duration of the current term of office: six financial years from May 3, 2017
Expiration date of the current term of office: at the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2022

## 2.1 Alternate statutory auditors

The appointment of an alternate statutory auditor is not required when the principal statutory auditor is not a natural person or a single-person legal entity.

During the period covered by the historical financial information, there have been no resignations or terminations of statutory auditors.

# SECTION 3
# 3. SELECTED FINANCIAL INFORMATION

The key financial information presented below was taken from the consolidated financial statements prepared according to IFRS [International Financial Reporting Standards]. It should be read together with the information contained in 99 "Examination of earnings and financial position", 10 "10and capital", and 20 "20information concerning the issuer's assets and liabilities, financial position and profits and losses".

Simplified consolidated balance sheet

| Consolidated data audited in €K | At December 31 | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Non-current assets | 5,842 | 3,956 | 3,704 |
| Including intangible assets | 2,343 | 1,838 | 2,100 |
| Including property, plant and equipment | 1,956 | 1,985 | 1,466 |
| Of which IFRS 16 rights of use | 1,370 | N/A | N/A |
| Including non-current financial assets | 173 | 133 | 138 |
| Current assets | 17,778 | 15,806 | 24,043 |
| Including cash and cash equivalents | 9,982 | 8,623 | 17,453 |
| TOTAL OF ASSETS | 23,621 | 19,762 | 27,747 |
| | | | |
| Equity | 253 | 7,979 | 16,744 |
| Non-current liabilities | 15,799 | 6,879 | 6,850 |
| Including long-term debt | 15,499 | 6,457 | 6,567 |
| Current liabilities | 7,570 | 4,904 | 4,153 |
| Including short-term borrowings and debts | 1,916 | 600 | 386 |
| TOTAL OF EQUITY AND LIABILITIES | 23,621 | 19,762 | 27,747 |

## Simplified consolidated income statement

| Consolidated data audited in €K | At December 31 | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Total sales of "equipment" | 2,301 | 2,683 | 3,101 |
| Total sales of "consumables" (probes) | 4,119 | 2,812 | 2,397 |
| Total sales of "services" | 1,011 | 1,265 | 1,188 |
| **Total sales** | **7,431** | **6,760** | **6,687** |
| Other income | 1,077 | 1,141 | 1,144 |
| **Total of revenue** | **8,509** | **7,901** | **7,831** |
| Cost of sales | (2,260) | (2,058) | (2,129) |
| Gross margin | 70% | 70% | 68% |
| **Total operating expenses** | **(21,537)** | **(19,899)** | **(17,541)** |
| Other operating income and expenses | - | - | - |
| **Operating Profit (Loss)** | **(13,028)** | **(11,998)** | **(9,710)** |
| **Profit before tax** | **(15,272)** | **(12,785)** | **(10,245)** |
| **Profit / (loss)** | **(15,272)** | **(12,785)** | **(10,245)** |
| Other comprehensive income | 75 | 128 | (174) |
| **Comprehensive income** | **(15,197)** | **(12,657)** | **(10,419)** |

## Simplified consolidated cash-flow statements

| Consolidated data audited in €K | At December 31 | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Net cash flows from operating activities | (10,272) | (10,900) | (9,742) |
| Of which self-financing capacity | (12,105) | (10,874) | (8,607) |
| Of which change in WCR related to business activities | 1,834 | (26) | (1,136) |
| Net cash flows from investing activities | (1,416) | (1,246) | (735) |
| Net cash flows from financing activities | 13,036 | 3,299 | 18,913 |
| Net foreign exchange difference | 10 | 16 | (35) |
| **Change in cash** | **1,359** | **(8,830)** | **8,401** |

## Net cash position

| Consolidated data audited in €K | 2019 | of which < 1 year | of which > 1 year |
|---|---|---|---|
| Financial debts | (17,415) | (1,916) | (15,499) |
| *Of which EIB loan* | *(10,616)* | | *(10,616)* |
| *Of which BPI loans* | *(3,423)* | | *(3,423)* |
| Cash and cash equivalents | 9,982 | 9,982 | - |
| **Net cash balances** | **(7,433)** | **8,066** | **(15,499)** |

***First Quarter 2020 sales:***

The Company reported its quarterly sales for 2020:

| Consolidated data in €K | At March 31 | | |
|---|---|---|---|
| | 2020 | 2019 | Change |
| Total sales of "equipment" | 555 | 558 | -1% |
| Total sales of "consumables" (probes) | 631 | 873 | -27% |
| o/w pay-per-use program | 302 | 331 | -9% |
| Total sales of "services" | 287 | 284 | 0% |
| Total sales | 1,473 | 1,715 | -14% |

Total sales for the first quarter of 2020 period were €1.5 million, down 14% year-over-year. First quarter 2020 sales performance was driven primarily by a 27% decrease in consumables sales and, to a lesser extent, a 1% decrease in system sales in the period. The year-over-year decrease in total consumables sales in the first quarter of 2020 was a result of lower procedure-related demand for Cellvizio probes in the Company's targeted commercial geographies around the world as a result of the COVID-19 pandemic. First quarter 2020 total sales performance benefitted from stronger-than-expected demand for Cellvizio systems in both the U.S. and APAC during the period.

# SECTION 4
# 4. RISK FACTORS

Investors are asked to consider all the information contained in this Universal Registration Document, including the risk factors described in this Section, before deciding whether to purchase or subscribe for shares in the Company.

To meet the requirements of this new "Prospectus 3" regulation, applicable since July 21, 2019, the presentation 4 the "Risk Factors" section of this Universal Registration Document has been revised to improve its readability.

In accordance with this new regulation, only material risks specific to the Company are presented in this chapter.

As of the filing date of this Universal Registration Document, the risks described below are those identified by the Company as likely to materially impact its business, image, financial position, results, ability to achieve its objectives and shareholders.

All identified risks and threats are regularly analyzed as part of the Company's risk management process.

The table below summarizes the main risks organized into four categories: risks related to the markets in which the Company operates, risks related to the Company's business/organization, financial risks, and legal risks.

In each of the 4 categories, the risks remaining after implementation of management measures are classified according to the criticality level (combination of the probability of occurrence and the estimated impact). Only those risks assessed with a "significant" level of criticality are discussed in this section.

Health and economic crisis related to the Covid-19 pandemic

The Company draws attention to the risks related to the health crisis related to the Covid-19 pandemic. This virus is actively circulating in a very large number of countries and measures restricting the movement of persons and interrupting or limiting certain human and industrial activities have been taken, particularly in France. In this environment, the Company is following the applicable directives and recommendations to protect its employees and subcontractors. The Company has therefore asked its employees in France to work from home and to organize remote meetings and events as much as possible. For employees who have to come to the premises, the Company has put in place a set of measures to ensure physical distancing and compliance with protective measures.

To date, the Covid-19 pandemic has had a material impact on the Company's commercial activities in the 1st half of 2020 with an overall drop of 47% compared to last year, due in particular to the 2nd quarter. However, this situation creates uncertainties about the future, which has led the Company to classify this risk with a "high" probability and an estimated "medium" 4.1.4see Section 4.1.4). The Company will continue to closely monitor the potential impact of the Covid-19 pandemic on how it conducts clinical studies and discussions with health authorities and, depending on how the epidemic crisis evolves and its potentially material impact on them, will inform the market.

Legend related to the criticality of risks:

| Probability of occurrence | | Estimated impact | | Degree of criticality | | Trend |
|---|---|---|---|---|---|---|
| *** | Probable | *** | High | *** | High | ⇗Increasing |
| ** | Possible | ** | Average | ** | Average | ⇨Stable |
| * | Unlikely | * | Low | * | Low | ⇘Decreasing |

| Risk factors | Probability | Impact | Criticality | Trend | Benchmark |
|---|---|---|---|---|---|
| Risks related to the markets in which the Group operates | | | | | |
| Risk of non-adherence to new technology | ** | *** | *** | ⇘ | 4.1.1 |
| Regulatory risks | ** | *** | *** | ⇨ | 4.1.2 |
| Risk of technological competition | ** | ** | *** | ⇗ | 4.1.3 |
| Risk related to the Covid-19 pandemic | *** | ** | ** | ⇨ | 4.1.4 |
| Risk related to the need for deployment in new indications | ** | ** | ** | ⇘ | 4.1.5 |
| Risk related to maintaining and obtaining reimbursement | ** | ** | ** | ⇘ | 4.1.6 |
| Risks related to the business/organization of the Group | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Risk related to dependence on a distributor network | ** | *** | *** | ⇨ | 4.2.1 |
| Risk related to dependence on suppliers | ** | *** | *** | ⇨ | 4.2.2 |
| Risk related to sales force loyalty | * | ** | ** | ⇘ | 4.2.3 |
| Risk of dependence on key persons | * | * | * | ⇘ | 4.2.4 |
| Financial risks | | | | | |
| Liquidity risk | *** | *** | *** | ⇨ | 4.3.1 |
| Risk related to historic losses | *** | ** | *** | ⇨ | 4.3.2 |
| Risk of dilution | ** | ** | ** | ⇨ | 4.3.3 |
| Risks related to the research tax credit | * | * | * | ⇘ | 4.3.4 |
| Risks relating to access to public advances | * | * | * | ⇨ | 4.3.5 |
| Exchange rate risk | * | * | * | ⇨ | 4.3.6 |
| Legal risks | | | | | |
| Risks relating to potential product liability | ** | * | ** | ⇨ | 4.4.1 |
| Risks relating to the warranty granted on the products sold by the Company | ** | * | ** | ⇨ | 4.4.2 |
| Risks related to intellectual property | * | * | * | ⇨ | 4.4.3 |
| Risk related to cybersecurity | * | * | * | ⇗ | 4.4.4 |

## 4.1 Risks related to the markets in which the Group operates

### 4.1.1 Risk of non-adherence to new technology

The products developed by the Company are positioned in markets in which, in some cases, alternative solutions already exist (traditional biopsy for example), the use of which is sometimes very widespread in the practices of physicians and other medical personnel.

The Group's development will depend in part on the pace at which healthcare professionals endorse its breakthrough technology.

The Group believes that healthcare professionals will not use its products widely until they are convinced, based on clinical data or scientific publications, that its products offer advantages or are an interesting alternative to equipment already on the market, which they are already experienced in using, and until its products are better covered (in full or in part) by the public or private healthcare insurance systems, depending on the geographic region.

In spite of the compelling results from clinical trials already conducted, the support of numerous specialty societies throughout the world, multiple scientific publications reporting the contributions of the solution proposed by the Company compared to technologies existing to date and the installed base of the Company's products, these same professionals could be reluctant to change their medical treatment practices in favor of the Cellvizio, particularly for the following reasons:

- their lack of experience in using the Cellvizio;
- a significantly insufficient amount of favorable clinical data published;
- fear of their possible liability for using new products, new operating procedures and the interpretation and integration of resulting new information (mainly in vivo microscopic images); and
- limitations on reimbursements by public or private health insurance plans or other health insurers.

Without the endorsement of healthcare professionals, the widespread commercial adoption of the Cellvizio could be more or less compromised, which might have a material adverse effect on the Group, its business, financial situation, earnings, growth and prospects.

### 4.1.2 Regulatory risks

The Group's products fall into the category of medical devices, whose control, manufacture and sale are subject to obtaining and maintaining regulatory approvals and certifications. All marketing authorizations are shown 6.3.4Section 6.3.4 of this Universal Registration Document. In fact, the Company's products are subject to strict and continually changing regulations shaped by efforts to harmonize standards, in particular the replacement of the European Directive 93/42/EC (on sales and free movement conditions of medical devices within the European Economic Area) by new European regulation of medical devices

or "RECAST[1]", approved and published by the European Parliament in May 2017 with a compliance deadline of May 2020 and which is reflected in stricter and more difficult requirements to apply.

The Company has launched an impact assessment of the European regulations on the compliance of its products in order to implement the necessary actions. However, compliance with this regulatory process can be long and costly, and there is no guarantee that authorizations will be obtained or of how long it may take to obtain or renew them. If certification or authorization to market the Company's products were refused, their marketing could be delayed or prohibited in the countries involved.

Similarly, even if the Company takes into consideration, as part of its business, the potential evolution of legislation or changes in standards or regulations applicable in the countries in which the Company markets and plans to market its products, particularly in the United States where the Company obtained around fifteen product authorizations, new regulatory restrictions could prevent the sale of the Company's products in the event of withdrawal or suspension of marketing authorizations, or could delay sales, in particular, by making their production more costly.

#### 4.1.3 Risk of technological competition

The Company cannot guarantee that other alternative or competing technologies with characteristics similar or superior in whole or in part to those of Cellvizio will not be developed, even if it believes that the other solutions available are less efficient than Cellvizio and its confocal mini-probes, in particular because they are more invasive and do not allow for microscopic visualization in vivo.

These technologies could acquire significant market share and limit the Group's ability to successfully market its products. Thus, they could prevent the technology integrated by the Company in Cellvizio (optical laser scanning) from becoming the standard for optical biopsy.

In particular, the leaders of the endoscopy market are major players in relation to the Company and have substantial financial resources, which could develop new technologies that are more effective, safer and/or less costly than those developed by the Group, which could lead to a drop in demand for the Group's existing products.

In addition, companies developing diagnostic solutions such as liquid biopsies, which would make it easier to analyze tumor cells and detect possible genetic mutations in order to better tailor the patient's treatment, could offer effective alternatives to tissue biopsy.

The Group's long-term success depends in part on its ability to improve and constantly expand the products it offers, to respond to the constantly changing demands of the market, withstand strong competitive and technological pressures,

In this regard and in addition to its intellectual property protection policy (see 11.2.111.2.1 of this Universal Registration Document), the Group is constantly monitoring technology, patents and products to be able to understand and anticipate change in its technological and business ecosystem. Thus, the Group continuously strives to improve its existing products and develop new products to provide solutions adapted to new areas of medicine and new pathologies, without compromising its technological progress.

However, the Group might be unable, in its current configuration, to satisfy these demands. The Company could in the near future make selective acquisitions of new or complementary technologies. The implementation of this strategy depends, in part, on the Company's ability to identify attractive targets, carry out such acquisitions on satisfactory conditions, and integrate them successfully into its operations or technology.

#### 4.1.4 Risk related to the Covid-19 pandemic

The emergence of a contagious disease, such as the new strain of coronavirus or Covid-19 that recently appeared in a large number of countries, may seriously disrupt the Company's business and have a material adverse effect on its operations, including its ongoing clinical studies, financial position and prospects.

The Covid-19 epidemic, which began in January 2020 in China and then reached several other regions of the world, has led the governments of a number of countries in which Mauna Kea operates to adopt confinement measures and restrict the movement of people and goods. On March 11, 2020, the World Health Organization officially classified this epidemic as a pandemic.

The Covid-19 pandemic is impacting the world economy, particularly the major economic regions, the United States, Europe and China, as well as that of many other countries in the world, and could impact the Company's business and those of third

1Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

parties on which the Company depends. Although the potential economic consequences of the Covid-19 pandemic and its duration are difficult to assess or predict, its impact on global financial markets could make it more difficult for the Company to access external financing. The impact of this crisis on the Company's share price remains difficult to precisely measure. However, if the high volatility and downward trend in stock prices should persist in the financial markets, the Company could be required to raise funds at a lower price per share, which would require it to issue more shares and ultimately cause greater dilution of its existing shareholders.

In addition, even though to date the Company has not experienced any major impact on its supplies, the fact that certain of the Company's suppliers of materials used in production are located in regions impacted by the Covid-19 pandemic could negatively affect supplies.

As of the date of this Universal Registration Document and given the general climate of uncertainty, it is impossible to predict the duration and extent of the potential damage of the current Covid-19 pandemic on the Company's research and development activities, healthcare systems and the global economy overall. However, these effects could significantly impact access to capital resources and the Company's operations and those of the third parties on which it depends.

#### 4.1.5 Risk related to the need for deployment in new indications

The Group's development is also conditional on its capacity to commercialize its products in new indications in the medical and research fields.

At the filing date of this document, the Group markets Cellvizio and its miniprobes in two markets: "Cellvizio LAB" is a specific version of the product targeted at research laboratories, while Cellvizio is sold to healthcare facilities (hospitals and clinics) in the areas of gastroenterology, pulmonology and urology. Confocal miniprobes used in clinical practice have a limited number of usages and thus generate recurring income.

The Company plans to continue its research and development efforts to perfect its existing products and develop new products and services to expand the medical applications that could benefit from data obtained in examinations using the Cellvizio.

From 2005 to this day, Cellvizio's clinical contributions have been reported in numerous publications. There are more than 1,000 clinical publications worldwide on endomicroscopy, including several randomized, multicenter clinical trials, including some key gastroenterology applications, funded by the Group.

The quality and interest of these multicenter clinical trials are linked to the Group's ability to select its partner healthcare facilities and to recruit sufficient numbers of patients in relatively short periods of time to be able to quickly publish the results. The distance or geographical distribution of the trial sites, even if rationalized, may also give rise to operational and logistical challenges which may generate additional costs and delays.

If the Group is unable to recruit the expected patients, resulting in delay of the clinical studies and the publication of their results, there would be a delay in the endorsement both by professional associations and by professionals from the relevant medical fields, and the Group's ability to market its equipment would be affected.

In addition, the Group is seeking to clinically validate the contributions of Cellvizio in new medical fields (urology, pulmonology, surgery, interventional radiology, neurosurgery and biomarkers, etc.). These studies are not systematically conducted by the Company as sponsor, and some are investigator-led. If the results of these studies, whether comparative (randomized studies) or not, do not make it possible to prove the medical advantage of the equipment offered by the Group, the medical community's recognition of the Cellvizio would be compromised.

If these risks occur, the Group's ability to win market share would be affected on a long-term basis, which might have a material adverse effect on the Group, its business, financial position, earnings, development or prospects.

#### 4.1.6 Risk related to maintaining and obtaining reimbursement

On the date of this document, the United States remains the main country where the Group has obtained reimbursement rates (see Section 6.3.46.3.4 of this Universal Registration Document). The Group's commercial development depends on its ability to preserve the level of reimbursements already granted by certain payers (private and public health insurers) and to extend reimbursements to other indications and geographical regions.

The governments and agencies responsible for public or private health insurance plans try to control health expenses by limiting both the level of reimbursement and the coverage of certain products, particularly innovative products like the Cellvizio and the Confocal MicroprobesTM. This pressure could even be strengthened in the current context of the Covid-19 epidemic, which involves a very significant financial mobilization of social and private insurance organizations and is likely to place in the very short term the question of health expenses and their rationalization at the heart of the public debate.

In spite of the clinical validation obtained, the Company cannot ensure that the Group will be able to obtain, in all the countries in which it wishes to market its products, firstly, these products' eligibility under the reimbursement conditions and, secondly, coverage and reimbursement levels that would encourage healthcare professionals to incorporate endomicroscopic procedures into their practices, nor can it ensure that it is or will be able to foresee potential changes over time in the coverage and reimbursement conditions that it could have obtained.

The absence of or insufficient reimbursement for or coverage of the Group's products or the adoption of more restrictive reimbursement or coverage measures might have a material adverse effect on the Group, its business, financial situation, earnings, growth and prospects.

## 4.2 Risks related to the business and organization of the Group

### 4.2.1 Risks related to dependence on a distributor network

The success of the international marketing roll-out of the Group's products in countries where the Group does not have a direct sales force, i.e. outside France, Germany, the United Kingdom, Benelux and the United States, depends largely on partners and distributors granted sector and territorial exclusivity and who market the technology under the Cellvizio brand name. To date, the Company has signed a number of exclusive distribution agreements in the countries in which it has marketing authorization, an updated list of which appears in Section 6.1 of 6.1Universal Registration Document. The Group cannot guarantee that it will be able to retain its existing distributors or enter into new distribution or partnership agreements to cover all countries with sales potential.

In addition, given that in general these distributors have several products, sometimes even products of their own manufacture, the Group cannot guarantee that they will devote the resources necessary for the commercial success of its products. In order to limit this risk, the Group has assigned part of its direct sales force the mission of helping its distributors carry out, in particular, face-to-face sales at trade fairs and demonstration sessions in healthcare facilities.

The risk of dependence is increased in certain regions or countries where the Company uses a limited number of distributors. Thus, in 2019, an APAC region distributor represented more than 31.7% of sales.

### 4.2.2 Risk related to dependence on suppliers

**The Company depends on a single partner for the supply of an important component.**

The Company is dependent on a single partner for the supply of optical fibers, an important component of its products, namely the Fujikura Group (and its subsidiary Fibertech), a Japanese conglomerate operating in multiple industries. This situation results from the Group's choice to develop its product using a certain type of fiber optics with very specific characteristics. For this reason, the Company has for several years sought to build a long-term partnership with Fujikura, which became a shareholder of Mauna Kea Technologies in November 2006, at the time of its capital increase, and holds 0.69% of the capital as of the date of this Universal Registration Document.

In addition, Fujikura carries out certain manufacturing steps and the assembly of a model of Confocal Miniprobes on behalf of the Company, which enables the Company to plan for increased production but further strengthens its relationship with this critical supplier.

The framework contract with Fujikura has been renewed twice (in 2015 and at the beginning of 2019). It is accompanied by a financial commitment by the Company to make a minimum purchase over a 3-year period, in exchange for the maintenance of, except in exceptional circumstances, the maximum price levels for products and services provided to the Company. This contract also includes a commitment to build up a safety inventory and to enable the transfer of the fiber optic manufacturing technology to a third party in order to ensure the Company's business continuity.

All of these reasons lead the Company to consider that the supply risk in respect of its partner is being managed correctly even though we cannot rule out a risk of contractual breach. The Company conducted technical evaluations of other sources in order to satisfy new developments or offset any breaking off of relations with Fujikura. However, such alternatives would require a period of adaptation of our product and the logistics chain, which could have a material adverse effect on the Company, its business, its earnings, financial situation, growth and prospects.

**The Company depends on third parties for the manufacture of its products.**

Since the Company depends on third parties to manufacture all of its products, its commercial success therefore depends in part on its ability to obtain from its subcontractors manufactured products compliant with specifications, on time and under acceptable financial terms. Problems could arise during their manufacture and distribution and could result in delays in the supply of products (particularly under exceptional circumstances such as a pandemic similar to the Covid-19 pandemic, which

may lead to a shutdown or limitation of operations of production equipment and/or the movement of people or products), which could result in higher costs, lower sales, a deterioration in customer relations and, in some cases, the recall of products causing damage to the Company's image and the risk of the Company being held liable.

Due to the regulatory status of the Company's products, this dependence is increased. In fact, a change in critical suppliers or subcontractors (optical fibers, optical lenses, opto-electronic components) for its equipment and consumables could require the process and procedures for manufacturing products to be revalidated in compliance with applicable standards. In this event, additional testing and validation may be required to maintain CE marking and other regulatory registrations, particularly in the United States. This procedure could be costly and time-consuming. Were these new authorizations to be denied, the Company could be forced to look for another supplier or subcontractor, or to keep its current suppliers and subcontractors, which might delay the production, development and marketing of its products and increase their manufacturing costs. In addition, if the relationship with one of its suppliers or subcontractors were to be terminated, the Company may be unable to find a subcontractor with the same skills within a sufficient time period or on commercially satisfactory terms.

In addition, although the Company has implemented a process to select and periodically assess its critical suppliers and subcontractors and performs compliance controls, the Company has less control over the compliance of the products manufactured by these third parties with regulatory standards, the quality control of its products, and the continuity of its operations in the event of a breach or non-renewal of these agreements, than it would have if it produced its products itself.

Even if the Company looks for new suppliers or subcontractors for its entire production and distribution chain, it cannot ensure that it will be able to enter into new agreements on acceptable commercial conditions, given the small number of specialized companies that have the infrastructure, experience and approvals and/or certifications permitting the production of this type of medical device. In the event of a breach or deterioration in its relations with its subcontractors, or when its needs increase, the Company might be unable to establish relations with other suppliers or subcontractors, which could be detrimental to its ability to produce, develop and market its products successfully.

#### 4.2.3 Risk related to sales force loyalty

The Group's commercial roll-out largely depends on its sales forces, and it might not be able to recruit and retain within the time periods or conditions compatible with its expansion.

In particular, in France, Germany, the United Kingdom, Benelux and the United States, the Company uses a direct sales force in gastroenterology and pulmonology applications, and its success in these territories depends in particular on its ability to recruit, train and retain this internal sales force.

#### 4.2.4 Risk of dependence on key persons

Given its size and competitive environment, the Group could lose key employees and may not be able to attract new qualified personnel under acceptable economic conditions, whereas its success, particularly for the development of its business, depends largely on the involvement and expertise of its managers, qualified personnel, and on additional recruitment.

The inability of the Group to attract and retain these key persons could prevent it from achieving its objectives overall, and thus have a material adverse effect on its business, earnings, financial situation, growth and prospects.

Thus, even though the Company has taken out "key person" insurance for three persons (see Section 21.3of this Universal Registration Document), the departure of one or more of these persons or other key employees of the Group could lead to:

- the loss of know-how and the undermining of certain activities, which would be exacerbated in the event of a move to the competition; or
- shortcomings in terms of technical abilities that could slow the business and could affect, going forward, the Group's ability to achieve its objectives.

In view of this risk, the Group has implemented contractual provisions specific to its business: non-compete clauses, non-enticement clauses, transfer of intellectual property clauses and confidentiality clauses. It has also set up systems for motivating and creating loyalty in personnel, in the form of compensation that varies based on performance and the award of financial instruments giving access to the Company's capital (share warrants (BSA), founders' warrants (BSPCE) or stock options).

### 4.3 Financial risks

Refer also to Note 24 to the consolidated financial statements for the year ended December 31, 2019, which appears in 20.120.1 of this Universal Registration Document.

### 4.3.1 Liquidity risk

The Group believes breakeven on an operating basis will take several years. Therefore, it considers that it will need to secure new financing, with equity and/or debt, to finance its operations within that time frame.

Cash flow relating to operating activities for the full year 2019 amounted to €10.3 million and cash flow from financing activities to €13.0 million.

At June 30, 2020, the Company had available cash of €4.2 million. Given:

- sales prospects,
- the granting of a repayable advance and a grant of €0.5 million,
- the drawdown of tranche 2 of the EIB loan for €6 million in July 2020,
- the receipt of a loan guaranteed by the French Government (PGE) of €4 million from BNP Paribas and Bpifrance,

the Company considers that it is in a position to meet its commitments until September 30, 2021.

The Company plans to seek additional funding in particular through capital increases or debt financing. Nonetheless, the Company cannot guarantee that it will obtain the required financing.

If it cannot obtain this financing, the Company could resize its operational plans, in particular by slowing or limiting the extent of its development.

In the future, the Group will continue to have significant financing needs to develop its technologies and market its products.

The level of the Group's financing needs and their scheduling over time depend on elements that are largely beyond the Group's control and could change, such as:

- higher marketing and sales development costs than expected, and slower progress than expected in terms of the technology's adoption by health professionals;
- higher costs and slower progress than expected in its research and development programs and in clinical studies;
- the costs of preparing, filing, defending and maintaining its patents and other intellectual property rights;
- the costs of responding to technological developments and to the market, and to ensure the manufacture and marketing of its products;
- higher costs and longer time periods than expected to obtain regulatory authorizations, including the time needed to prepare applications for the regulatory authorities; and
- new opportunities for the development of new products or the purchase of technologies, products or companies.

The Company may be unable to raise additional capital when needed, and this capital may not be available at financial conditions that are acceptable to the Group, including, among others, the high stock market volatility of medical technology companies. If the necessary funds are not available, the Company could have to:

- reduce its sales and marketing expenses or stop marketing in unprofitable geographic areas;
- delay, reduce or end research programs;
- obtain funds through partnership agreements that could require it to waive rights to some of its technologies or products;
- grant licenses to its technologies to partners or third parties; and
- enter into new collaboration agreements that could be less favorable than those it might have obtained in a different context.

Furthermore, if the Company raises capital by issuing new shares, the stakes of its shareholders could be diluted. Debt financing, if available, could also include restrictive conditions for the Company.

#### 4.3.2 Risk related to historic losses

The Group has a history of operating losses, losses which could continue.

The Group has recorded operating losses every year since it began operations in 2000. The cumulative net losses (including carry-forwards) came to €130,758 thousand, including a net loss of €15,272 thousand for the financial year ended December 31, 2019. These losses are due mainly to research expenses, costs of development and sales and marketing expenses incurred.

The Group could experience additional operating losses in the coming years, as it pursues its research and development and marketing activities, especially in view of:

- the expansion of its portfolio of products intended for new medical sectors of application;
- the need to conduct new clinical trials to accompany the marketing of the Cellvizio on new medical sectors;
- the development of its research and development activities and, perhaps, the purchase of new technologies, products or licenses;
- commercial deployment that stretches beyond the gastroenterology market;
- increased regulatory requirements regarding the manufacture of its products; and
- more recently in its new business strategy, the increase of its fixed base of systems made available under its consignment model in its American market.

An increase in these expenses could have a material adverse effect on the Group, its business, financial situation, earnings, growth or prospects.

#### 4.3.3 Risk of dilution

Shareholders of the Company are exposed to a significant risk of dilution given the financing requirements described above, and also if shares are issued as part of any external growth transaction by the Company.

Dilution may also result from the issue or award of new financial instruments that give access to the Company's capital as part of its incentive policy for managers and employees.

Thus since its formation, the Company regularly issued or awarded stock options, warrants ("**BSA**") and founders' warrants ("**BSPCE**") and, since 2016, preferred shares.

The full exercise of all instruments that give access to capital awarded and in circulation at the date of this Universal Registration Document (including the instruments issued or awarded since December 31, 2019, i.e. the 500,000 warrants issued to the European Investment Bank, 15,000 stock options and 100 preference shares) would enable the subscription of 5,380,167 new shares, thus generating dilution equal to 15.0% on the basis of the capital existing to date. The dilution in voting rights would come to 14.5% on the basis of the voting rights existing to date.

As part of this incentive policy for managers and employees, the Company could in the future issue or award new financial instruments giving access to the Company's capital. Any additional share or issuance of financial instruments would result in a potentially significant additional dilution for the Company's shareholders.

#### 4.3.4 Risks related to the research tax credit

To finance its business, the Company benefited from repayment of the Research Tax Credit ("**CIR**") by the French tax administration with respect to some of its research and development expenses. The Company was subject to two tax audits for all taxes of 2009-2010 and 2014-2015, including the Research Tax Credit. No tax adjustments were necessary.

As regards 2017 and the following years, it cannot be ruled out that the tax authorities may challenge the methods used to calculate the Company's research and development costs, or that the CIR may be challenged due to a change in regulations, even if the Company complies with the documentation and eligibility requirements regarding costs. If such a situation were to occur, it could have an adverse effect on the Group's earnings, financial situation and prospects.

Every year, an amount was repaid by the tax authorities on account of the CIR within nine to twelve months following the filing of the tax return.

The following table describes the changes in the Research Tax Credit during the 2017 to 2019 financial years:

| (in €k) | 12/31/2019 | 12/31/2018 | 12/31/2017 |
|---|---|---|---|
| Research Tax Credit | 997 | 1,097 | 1,096 |

#### 4.3.5 Risks relating to access to public advances

At December 31, 2019, the Company benefited from the following aid:

| At Dec. 31, 2019 (in €k) | Amount granted | Amount receipt | Amount repaid | Discount effects | Amount still to be repaid |
|---|---|---|---|---|---|
| BPI France loans | 2,766 | | | 527 | 3,431 |
| **Total advances received** | **2,766** | | | **527** | **3,431** |

If the Group does not comply with the contractual conditions of the repayable advance agreements with BPI France as part of the PERSEE project, the Company could be forced to repay the sums advanced in advance (refer to Note 11 to the consolidated financial statements for the year ended on December 31, 2019 presented in Section 20.1 "Consolidated financial 20.1prepared under IFRS for the year ended December 31, 2019" of this Universal Registration Document). In 2019, the Company obtained the agreement of BPI France to extend the term of Phase 4 until October 31, 2020, the end of the project. Non-compliance with certain commitments of this Phase 4 could result in a partial payment of the sums remaining due by BPI France to the Company. Furthermore, the Beneficiary Contract governing the PERSEE project stipulates that early repayment may be demanded by OSEO in the event of a contribution/merger/split/change in control of the Company or disposal of its assets. Such situations could deprive the Company of some of the financial resources needed to successfully carry out its research and development projects.

#### 4.3.6 Exchange rate risk

The Group's major exchange rate risk is linked to changes in the EUR/USD exchange rate. In fact, the Group markets the product and services in the United States through its subsidiary Mauna Kea Technologies Inc. Its revenues and expenses – including the purchases of Cellvizio and probes to Mauna Kea Technologies SA – are expressed in US dollars, the operational currency of the subsidiary. As a result, the Group is exposed to changes in the EUR/USD exchange rate through that subsidiary.

A change in exchange rates has an impact on Group earnings and shareholders' equity in the same manner, as follows:

- a +10% change in the EUR/USD exchange rate would result in a rise in earnings of €499 thousand at December 31, 2019;
- a -10% change in the EUR/USD exchange rate would result in a drop in earnings of €(610) thousand at December 31, 2019.

The Group regularly assesses its exchange rate risk exposure and may decide, if necessary, to limit these risks through hedging.

### 4.4 Legal risks

#### 4.4.1 Risks relating to potential product liability

The Company's products are categorized as medical devices and, as such, are subject to specific regulations in all the countries in which they are manufactured, tested or marketed. These regulations and standards impose obligations, in particular with regard to:

- design;
- pre-clinical tests and clinical tests of products;
- manufacture, quality control and quality assurance of the products;
- labeling of the products, including instructions;
- storage of the products;
- identification and traceability of the products;
- procedures for data preservation;

- oversight subsequent to market introduction and reporting of incidents related to the use of the products.

These regulations and standards apply to the Company as the manufacturer of these products.

The principle of complete traceability of all the product's critical components, as well as the implementation and continuation by the Company of a Quality Management System (QMS) certified compliant with international standard ISO 13485 and a lean manufacturing system seeking to guarantee full compliance of each product with regulations applicable as well as its quality.

While the Company has put in place a supplier selection and monitoring system, it cannot guarantee that its suppliers or subcontractors comply or will comply at all times with the applicable regulations. The body notified, in the event of a certification or follow-up audit, or the regulatory authorities, during an inspection or at the time of any other regulatory process, might identify breaches of the regulations or standards applicable and require that the breach be remedied by corrective actions that might interrupt the manufacture and supply of the Company's products. The suspension, total stoppage, or total or partial prohibition of the activities of the Company's suppliers might materially affect the business, financial situation, earnings and reputation of the Group.

The Group could be exposed to risks from liability arising from the clinical development or commercial exploitation of its products, especially product liability. Criminal or civil proceedings might be brought or filed against the Group by users (patients, practitioners, researchers and other professionals in the fields of healthcare or research), the regulatory authorities, distributors or any other third party that uses or markets its products.

To date, the Group has not been the subject of any criminal or civil case in this area and has taken out product defect liability insurance that provides maximum coverage of €4 million per insurance year, increased by $5 million per insurance year for the United States.

The Company cannot ensure that its current insurance coverage is sufficient to respond to liability actions that may be brought against it. If it was held liable, and it was unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to protect itself in any way against product liability suits, this would seriously affect the marketing of its products and, more generally, be detrimental to the business, results, financial situation, growth and prospects of the Group.

#### 4.4.2 Risks relating to the warranty granted on the products sold by the Company

In parallel to the implementation and continuation of a Quality Management System (QMS) certified compliant with international standard ISO 13485:2016, seeking that its products meet strict quality criteria, the Company generally grants its clients a one-year product warranty from the delivery date of the products. This warranty covers material defects as well as compliance of the products delivered with the technical descriptions and characteristics; it is limited to initial purchasers of the Company's products and cannot be transferred.

The Company has purchased a policy that covers the principal insurable risks and has the coverage amounts it deems compatible with the nature of its business. Although the financial consequences of the risk of this contractual warranty's being enforced were expected, the Company cannot ensure that these current provisions are sufficient to satisfy the enforcement of the contractual warranty by all its clients. If its liability were thus called into question, and if it were unable to obtain and maintain an adequate provision, or to protect itself in any way against the enforcement of this contractual warranty, this would seriously affect the marketing of products and, more generally, be detrimental to the business, results, financial situation, growth and prospects of the Company.

#### 4.4.3 Risks related to intellectual property

The Company counts, to a great extent, on the exclusive nature of its intellectual property and know-how. However, the Company might not be able to maintain or obtain adequate protection and, in this way, to protect its technological and competitive advantage.

The Company relies, for the protection of its products and technology, on the protection provided by intellectual property rights, such as patents covering both the hardware and software aspects of its current products, but also a number of alternative technologies or processes under development, trademarks, but also on its trade secrets and its know-how covering, in particular, manufacturing methods and the choice of certain critical components protected by confidentiality or other agreements. However, these means provide only limited protection and might not prevent unlawful use of the products or technology of the Group.

The Company could experience difficulties in obtaining some of its patent applications currently being examined. Furthermore, the issuance of a patent does not ensure its validity or applicability, both of which may be disputed by third parties. In addition, the Company has not, to date, filed patent applications in all the countries in which it operates, even though its patents or patent applications are most often filed in the United States, certain countries in Europe, Canada, Japan, Australia, and, for the most important patents, in China, India and Israel.

The Company cannot ensure with certainty that:

- the Company's patent applications that are in the process of being reviewed will actually result in the issuance of patents and accordingly in protection of the inventions covered by the patent applications in question in all the countries where these patent applications 11.2refer to Section 11.2 "Patents and patent applications" of this Universal Registration Documents), showing the patents obtained and the patent applications currently pending);
- the patents issued to the Company will not be disputed, invalidated or circumvented;
- the extent of the protection provided by the patents will be sufficient to protect it against competition and the patents of third parties that cover similar products or devices;
- the competitors of the Group have not already developed a technology or products similar to those of the Group; and
- the Group's products do not infringe patents that belong to third parties.

The Group's competitors may thus successfully challenge the validity of its patents before a court or in the context of other proceedings, which, depending on the outcomes of said challenges, could reduce the scope of these patents, lead to their invalidity or enable competitors to circumvent them. Therefore, the Company's rights under its patents might not provide the expected protection against competition.

Nor can the Company ensure that its products and technology, which are closely linked to its know-how and commercial secrets, are adequately protected against competitors and cannot be usurped, or circumvented, by the latter. Indeed, in the collaboration and research and development agreements entered into by the Company, the latter must frequently provide its co-contractors, in various forms, with certain items from its know-how, whether protected by patents or not, in particular information, data or knowledge concerning research, development, the manufacture and marketing of its products.

The Company seeks to limit the disclosure of key items from its know-how to third parties only to the information strictly necessary for the collaboration which it maintains with them and it ensures contractually that these third parties undertake not to misappropriate, use or disclose this information, in particular by means of confidentiality clauses. The Company cannot, however, ensure that these third parties comply with these agreements, that the Company will be informed of a breach of these clauses, or further that the damages it could possibly obtain would be sufficient in respect of the loss suffered.

Moreover, these collaboration and research and development agreements expose the Company to the risk of seeing its co-contractors claiming the benefit of intellectual property rights to the Group's inventions, knowledge or results. Lastly, these agreements could give rise to co-owned intellectual property rights or to the granting of exclusive licenses under conditions unfavorable to the Group.

The Company's trademarks are important elements of its identity and its products. Even though the Cellvizio trademark has been registered in France, Europe and the United States in particular and in numerous countries, third parties could use or attempt to use this trademark or other trademarks of the Company, which would be of a nature to cause a commercial loss and harm the image of the Group.

The Company's protection of its intellectual property rights accounts for a considerable cost relating, in particular, to the expense of registering patents and keeping them in force and to managing its other intellectual property rights, the costs of which could increase, in particular if litigation were to be brought by the Company to assert its rights. In addition to these costs, if litigation were to prove necessary in order to enforce compliance with the Company's intellectual property rights, to protect its trade secrets or know-how or to determine the validity and scope of its intellectual property rights, it could have a negative influence on earnings and the financial situation of the Group, or fail to provide the protection sought.

Similarly, monitoring the unauthorized use of products and technology is difficult, and the Company cannot be certain that it will be able to avoid misappropriations or unauthorized use of its products and technology, in particular in foreign countries where its rights might be less well protected.

The materialization of one or more of these risks could have a material adverse effect on the Group's business, financial situation, earnings, growth and prospects.

In the future, some of the Company's business could depend on technologies belonging to third parties.

The Company benefits from two exclusive licenses for third-party technologies, namely INSERM-APHP and the University of Denis Diderot (Paris 7).

The Company is not currently using the technology covered by this license agreement, but it could be incorporated into future products, depending on the result of the research and development work currently underway.

Any violation by the Company of the conditions of these licenses may lead to loss of the right to use the technology in question.

For the success of its business, it is important that the Company be able to exploit its products and technology freely in regard to patents or intellectual property rights of third parties.

Given the intense competition in its field, the Company cannot guarantee that there are no patents or other intellectual property rights of third parties that may apply to certain of the Company's activities, products or technologies enabling these third parties to bring a legal action for infringement, or for a similar ground, against the Group in order to obtain damages or the cessation of the use of the product or process in question.

If these legal actions are carried out to conclusion and acknowledged, in full or in part, to have foundation, the Group could be forced to stop or delay the research, development, manufacture or sale of products or processes affected by these actions, which could significantly affect its activities.

In particular, the Group could be required, in addition to paying financial compensation, to:

- stop manufacturing, selling or using the products or technology called into question, in a given geographic zone, which could reduce its revenue;
- obtain, under conditions unfavorable to the Group, a license to the third-party intellectual property rights; and
- find alternative solutions in order to avoid infringing the intellectual property rights of third parties, which could turn out, in some cases, to be impossible or costly in terms of time and financial resources, and could thus be an obstacle to its marketing efforts.

A lawsuit brought against the Group, regardless of the outcome thereof, could moreover result in substantial costs, disorganize its operation, and compromise all or part of its business, image and reputation.

#### 4.4.4 Risk related to cybersecurity

The digital transformation carried out by the Group over the last few years has had the consequence of greater exposure to the risks related to cyber attacks as well as those related to the failure of IT and communications systems. These risks are increasingly important in the execution of day-to-day data processing, storage and transmission transactions.

In addition, certain tools and applications required for the Group's business are hosted by service providers on which the Group depends. IT outsourcing generates uncontrollable risks and requires close monitoring of our IT subcontractors to guard against various cyberattacks:

- viruses and malware;
- fraudulent emails;
- piracy;
- industrial espionage;
- embezzlement;
- the loss of confidential information; and
- handling errors.

In addition, the strengthening of regulations regarding personal data protection (GDPR) are increasing risks related to regulatory non-compliance.

The Group has taken a number of necessary measures to comply with legal obligations in terms of:

- cybersecurity of data (GDPR). These measures must be both material (security of the premises), administrative (procedures for restricting access to information) and technical (use of passwords and encryption);
- the protection of the intangible and informational assets; and
- protection mechanisms against cyber attacks on individuals.

However, the Group cannot guarantee that the risks related to cybersecurity in an environment where digitalization is continually increasing are totally secure.

# SECTION 5
# 5. INFORMATION ABOUT THE COMPANY

## 5.1 History and growth of the Company

### 5.1.1 Corporate name of the Company

The corporate name of the Company is: Mauna Kea Technologies SA.

### 5.1.2 Registration place and number of the Company

Mauna Kea Technologies was registered in the Paris Trade and Companies Register on May 3, 2000 under the unique registration number 431 268 028.

### 5.1.3 Date and term of incorporation

The Company was incorporated for a term of 99 years ending May 3, 2099, except in the case of early winding up or extension.

### 5.1.4 Registered office of the Company, legal form, legislation governing its business activities

The Company was first incorporated as a Simplified Joint Stock Company [société par actions simplifiée] and was transformed into a public limited company [société anonyme] by a decision of the General Meeting of partners on May 25, 2011.

The Company is subject to French law for its operations, primarily Articles L. 225-1 et seq. of the French Commercial Code.

The registered office of the Company is located at: 9 rue d'Enghien, 75010 Paris, France. The contact information for the Company is as follows:
Telephone: +33 (0)1 48 24 03 45
Fax: +33 (0)1 48 24 12 18
E-mail: investor@maunakeatech.com
Website: www.maunakeatech.com

### 5.1.5 Significant events in Company history

**2000**
The Company is created after the project wins the first competition for assistance in creating innovative enterprises ("concours d'aide à la création d'entreprises innovantes") in the "emerging" category in July 1999 and wins the Aventis Foundation award in January 2000.

The Company wins at the national level of the second competition for assistance in creating innovative enterprises in the "creation-development" category.

€1.6 million investment from a group of French entrepreneurs, including:
Marc Vasseur (Genset),
Jérôme Chailloux (Ilog, Genset),
Jean-Luc Nahon (Softway, Isdnet),
Christophe Bach (Isdnet), Patrice Giami (Isdnet),
Philippe Maes (Gemplus) and Daniel Legal (Gemplus) – through their Finadvance Ventures fund - and Jacques Attali.

**2002**
The first OSEO innovation aid is obtained.

**2004**
Delivery of the first two Cellvizio LABs to the laboratory of Alan Koretsky at the NIH (National Institutes of Health) and to the laboratory of Chris Contag in Stanford.

Creadev, Mulliez family, acquires a stake in the capital of Mauna Kea Technologies as a reference shareholder in July.

**2005**
Creation of the U.S. subsidiary Mauna Kea Technologies, Inc.

Obtained CE marking for the Cellvizio®'s applications falling within the fields of gastroenterology and pulmonology.

Obtained FDA (Food and Drug Administration) approval for the marketing of the Cellvizio in the United States for the applications falling within the fields of gastroenterology and pulmonology.

First images of patients made with the Cellvizio®.

**2007**
Signing of a distribution agreement for the Cellvizio LAB with Leica Microsystems in order to cover the research laboratories market.

Launch of the Cellvizio® for the applications in gastroenterology. The Mayo Clinic of Rochester is the first U.S. hospital to become equipped, followed shortly thereafter by the Mayo Clinic of Jacksonville.

In December, a €20.3 million private placement is made with Psilos Group, Health Evolution Partners, Seventure and Creadev.

**2008**
Mauna Kea Technologies is the only French company to obtain the Wall Street Journal Innovation award.

Launch of two multicenter clinical trials in the field of cancer of the esophagus and cancers of the biliary ducts.

Obtained the "OSEO-Innovative Enterprise" label.

**2009**
First ever ICCU (International Conference of Cellvizio® Users), a conference for the community of Cellvizio® users; 45 physicians attended in Miami Beach (United States).

Launch of Cellvizio.net, the first educational site on endomicroscopy for the Cellvizio® user community.

Signing of a worldwide distribution agreement with VisualSonics for its range of Cellvizio LAB instruments, as the agreement with Leica Microsystems did not enable reaching the anticipated objectives.

Launch of the NeuroPak, the first instrument in the world making deep brain imaging of live animals possible at microscopic level.

**2010**
Second annual ICCU conference with 67 physicians meeting in Paris, France.

Obtained a €7.6 million award from OSEO, €4.9 million of which going to the Company (grant for €1.5 million and repayable advances of €3.4 million), for an industrial research and development project led by Mauna Kea Technologies (PERSEE project).

More than 20 studies on the Cellvizio® in gastroenterology are presented exclusively at the international Digestive Disease Week (DDW) conference.

**2011**
IPO on the regulated market of NYSE Euronext in Paris (compartment B) with €56.5 million in funds raised (July).

Launch of the Cellvizio® Series 100 version at the third annual ICCU conference with 96 physicians attending in Nice.

Launch of version 2 of Cellvizio.net, which boasts 600 active members.

Partner of the UHI project, named the winner of the "Investissements d'Avenir IHU [UHI Future Investments]" call for projects with an allocation of €67.5 million. This project will enable a world center for excellence in the field of mini-invasive image-guided surgery to emerge.

Influential participation at the international Digestive Disease Week (DDW) conference in Chicago where 36 presentations on the Cellvizio® were given, including two during presidential sessions and two in plenary sessions on the major results of the significant clinical trials sponsored by the Group.

Obtained 510(k) approval from the FDA to market the new-generation Cellvizio® in the United States, named Cellvizio® 100.

Obtained CE marking for Cellvizio® 100 in April 2011.

**2012**
Fourth annual ICCU conference with 123 physicians attending in Rome.

Obtained three Category I CPT reimbursement codes in the United States to use the Cellvizio® in the upper digestive tract, awarded by the American Medical Association (AMA) selection committee.

Obtained a reimbursement rate of $927 from Medicare/Medicaid in the United States for the use of Cellvizio® in the upper digestive tract.

**2013**

Fifth annual ICCU conference with more than 200 participants, including 25 experts, in Versailles.

Entry into force of these reimbursement codes (Category I CPT Codes) on January 1.

Marketing authorization for the AQ-Flex™ 19 confocal miniprobe in the United States for use in fine needle aspiration procedures.

Assignment of an OPS code in Germany for the reimbursement of endomicroscopy using Cellvizio® in gastroenterology.

**2014**

Sixth annual ICCU conference with more than 260 participants, including 85 experts, in Opio.

Enactment by US health authorities of practitioner compensation for practitioners performing Cellvizio® procedures in the upper digestive tract.

Reassessment of the reimbursement rate from $927 to $1,013 in early 2014.

Obtained 510(k) regulatory approval from the FDA in urology for the use of the Cellvizio® via Uroflex™ B and CystoFlex™ F Confocal Miniprobes.

Installing the first Cellvizio® system in India at the Apollo Gleneagles Hospital in Kolkata, the flagship hospital for gastroenterology in India and a member of the Apollo Hospitals Group.

Obtained class 1 regulatory authorization from the Japanese Ministry of Health, Labor and Social Protection (MHLW) to use the Cellvizio® technology and class 2 regulatory authorization (NINSHO) for the endoscopic use of confocal miniprobes.

Obtained 510(k) regulatory approval from the FDA for a new Cellvizio® using an infrared wavelength.

French Health Authority authorizes the reimbursement of endomicroscopy in patients with Barrett's esophagus.

Mauna Kea Technologies receives regulatory approval in Brazil

Partnership agreement signed with Siemens to evaluate the use of endomicroscopy with Cellvizio® in interventional radiology procedures.

**2015**

Seventh annual ICCU conference with more than 300 participants, including 85 experts, in Lisbon.

Publication of the FOCUS pivotal trial in Gastrointestinal Endoscopy, confirming the high accuracy of Cellvizio® in the diagnosis of bile duct cancer during endoscopic retrograde cholangiopancreatography (ERCP).

Publication in the United European Gastroenterology (UEG) Journal of a clinical consensus report endorsed by 26 international experts on the use of endomicroscopy in gastroenterology.

Publication of two studies showing that endomicroscopy provides real time identification of healthy and cancerous tissue during breast-conserving surgery. Publication of results of a clinical trial on the use of the Cellvizio® in the scientific journal Breast Cancer Research and Treatment.

Obtained a CPT reimbursement code in the United States for a Cellvizio® biliary application.

Marketing authorization for the Cellvizio® received from the Mexican Health Authority.

Capital increase through a private placement, leading to the issuance of 1,189,251 new shares and raising a gross amount of €4.7 million.

Obtained CE marking in indications of minimally invasive laparoscopic surgery.

CE marking obtained for interventional radiology.

CE marking obtained for the new perioperative platform Cellvizio® 800.

Regulatory approval obtained in Japan for the AQ-Flex™ 19 confocal endomicroscopy miniprobe.

510(k) clearance obtained from the FDA for the use of Cellvizio® in surgery, allowing identification of cancerous tissue and effective guidance of treatment during surgery.

Obtained regulatory authorization in China to sell the latest generation Cellvizio® 100s as well as for the probes dedicated to pancreatic and urological applications.

Signed a master agreement with Cook Medical for urological applications.

**2016**

Listed on the OTCQX market in the USA.

Extension of strategic partnership with Fujifilm China.

Exclusive urology partnership with Cook Medical.

Clinical research collaboration with the Scottish company, Edinburgh Molecular Imaging.

FDA authorization for the marketing of miniprobes for near-infrafred surgery.

Endorsement of the Cellvizio® by the American Society of General Surgeons (ASGS).

Increase in reimbursement rates at hospitals (+131%) and ambulatory

surgical centers (+86%) in the United States.

Completion of the recruitment of 200 patients for the CONTACT II trial on the diagnosis of pancreatic cysts using fine needle-based confocal laser endomicroscopy (nCLE).

The first study on the contribution of Cellvizio® to pediatric heart surgery is launched.

The CONTACT clinical study confirms the clinical effectiveness of Cellvizio® needle-based endomicroscopy in the diagnosis of pancreatic cysts.

Publication of the results of the PERSEE study in "Surgical Endoscopy" and the "European Journal of Gastroenterology & Hepatology".

**2017**

*Gastroenterology*

Publication of a general overview of the Singapore Gastric Cancer Consortium team in a peer-reviewed journal highlighting the superior performance of endomicroscopy in terms of diagnostic yield improvement in gastric cancer.

Publication of a new study highlighting the strong performance of needle-based confocal laser endomicroscopy (nCLE) in the diagnosis of pancreatic cysts.

Clinical results obtained with confocal laser endomicroscopy highlighted in 27 physician oral presentations on current and emerging applications of Cellvizio® during the Digestive Disease Week (DDW) conference held in Chicago.

Publication of a new study in the World Journal of Gastroenterology, a peer-reviewed journal focused on the field of gastroenterology and hepatology.

Peer-reviewed publication of key multicenter randomized controlled trial demonstrating improved early stomach cancer detection with Cellvizio®: diagnostic yield more than doubled while number of necessary biopsies reduced by half and no change in procedure time.

Publication of a French health economics study showing a significant reduction in clinical costs through the diagnosis of benign pancreatic cysts with Cellvizio®.

*Urology*

Publication of a new study supporting the use of Cellvizio® in urology for the real-time histological characterization of upper tract urothelial carcinoma (UTUC) lesions.

*Pneumonology*

Presentation of new data demonstrating the applicability of Cellvizio® in assessing acute lung rejection following transplant at the American Thoracic Society (ATS) annual conference.

Obtained CE marking and authorization in the United States to market the use of CelioFlex™ UHD confocal miniprobes with Cellvizio® during robotic surgery procedures.

Obtained marketing authorization in the United States for the use of Cellvizio® to visualize the internal microstructure of tissues and also identify, among others, cells and vessels and their organization or architecture.

Healthcare cover for procedures using Cellvizio® now provided in Croatia for patients with gastrointestinal, biliopancreatic, respiratory and urinary disorders with reimbursements ranging from €250 to €800.

The FDA validates the cell and vessel identification and their organization or architecture in vivo and in real time with the Cellvizio 100 series and all its confocal miniprobes.

**2018**

*Gastroenterology*

Positive assessment obtained from the Korean National Evidence-based Healthcare Collaborating Agency (NECA). New Health Technology Assessment (nHTA) Committee recognizes confocal laser endomicroscopy as "a safe and effective technology in application for esophagus, stomach, bile duct". New Health Technology status enables specific reimbursement codes for Cellvizio® procedures in South Korea, third largest medical market in Asia.

Cellvizio® Demonstrates Superior Identification of Patients at Risk for Esophageal Cancer Compared to Current Diagnostic Standard. The results of the study on 172 patients recruited in 8 non-university centers in the United States were presented at the 2018 World Congress of Endoscopic Surgery organized by the companies SAGES and CAGS.

Discovery of a new structure in the human body. The study conducted on the initiative of researchers who used Cellvizio® to characterize an unknown structure, the "interstitium", up to now never identified by standard histological techniques. According to the publication in Scientific Reports, this discovery may have significance in cancer metastasis and could lead to new therapeutic approaches for cancer.

20 presentations focusing on Cellvizio®'s clinical value were given during the DDW conference on Barrett's esophagus, Inflammatory Bowel Disease /Syndrome (IBS/IBS), pancreatic cysts and other gastrointestinal diseases.

Publication in Surgical Endoscopy of the positive results of a prospective American multicenter clinical trial on the detection of Barrett's esophagus with Cellvizio® by new users.

*Pneumonology*

Obtaining U.S. Food and Drug Administration (FDA) 510(k) clearance of the Cellvizio® 100 series F400 and F800 with a new Confocal Miniprobe, the

CranioFlexTM, to be used during neurosurgical procedures. This marks the 15th U.S. FDA 510(k) clearance of Cellvizio® and the first- ever FDA clearance for CLE applications in neurosurgery.

Publication of a prospective multicenter study that demonstrates the potential of Cellvizio® to aid in the diagnosis of acute cellular rejection in lung transplant patients. Cellvizio®'s optical biopsy could become a safe and effective alternative to invasive biopsies in transplanted patients.

Publication in Surgical Endoscopy of the positive results of a prospective American multicentric clinical trial on the detection of Barrett's esophagus with Cellvizio®. This publication is additional validation of Cellvizio's superior sensitivity in the detection of Barret's esophagus compared to the standard protocol and the major progress that this represents in terms of identifying individuals at risk for esophageal adenocarcinoma.

The Company presents its Cellvizio need-based endomicroscopy for applications in lung cancer and other lung diseases during the European Respiratory Society (ERS) international congress, the largest gathering of lung disease specialists in the world, held in September in Paris.

First publication on the use of "Tele-Cellvizio" in vivo and in real time between surgeons and histopathologists. The results of the PERSEE trial involving the teletransmission in real time and the robotic use of the Cellvizio miniprobe are published online in Surgical Endoscopy. Perioperative intraocular confocal endomicroscopy in real time with near-infrared illumination provides additional information in terms of tissue characterization and, in combination with in vivo telepathology, allows interactive collaboration between the surgeon and the histopathologist during surgical procedures.

The results of Contact 2 attained all its primary and secondary clinical evaluation criteria showing a higher diagnostic performance of Cellvizio than the technical standard of care for patient with pancreatic cystic lesions (PCLs). The study showed a very high sensitivity and specificity of the nCLE criteria for the specific diagnosis of single cystic tumors not connected to the pancreas. The systematic addition of nCLE to standard procedures had a positive impact on therapeutic decisions and offers significant economic benefits for patients and hospitals.

**2019**

*Indebtedness*

On May 29, 2019, the Company announced the subscription of a €5 million tranche from IPF Partners as part of the amendment to its debt agreement signed on November 13, 2018.

In addition, the Company repaid this financing in advance. The two bond tranches issued for €4.0 million and €5.0 million respectively in February 2017 and May 2019 were fully repaid on June 28, 2019 for a total amount of €10.7 million. The refinancing of this debt saves €2.0 million in interest over the next five years.

Following the financing agreement with the European Investment Bank (EIB), the Company received the first tranche of €11.5 million on July 3, 2019.

Tranche 1 is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of October 5, 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants may be exercised from this day until the twentieth anniversary of the issuance of the warrants, i.e. July 3, 2039.

*Capital increase*

The capital increase reserved for Johnson & Johnson Innovation Inc. was completed on December 16, 2019 resulting in their payment of €7.5 million following the issue of 5,357,142 new ordinary shares for a unit subscription price of €1.40 thus bringing the company's stake in Mauna Kea Technologies to 17.5%.

This capital increase is intended to fund day-to-day operations, particularly in the areas of clinical trials, development activities and sales and marketing in the United States.

*Repayment*

Coverage of esophageal endomicroscopy procedures in France, in particular for Barrett's esophagus, through the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM).

The tariffs reimbursed are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for anesthesia (Activity 4). This UNCAM's decision will take effect 30 days after its publication.

Publication of a new 510(k) authorization from the U.S. Food and Drug Administration (FDA) for the use of the AQ-Flex™ 19 confocal miniprobe through trans-bronchial needles with bronchoscopes and existing bronchoscopy accessories. This is the 16th 510(k) authorization received from the U.S. FDA for the Cellvizio® platform.

Publication of a prospective study (ClinicalTrials.gov Identifier: NCT02689050) demonstrating Cellvizio's potential as a diagnostic and evaluation aid in lung cancers. The results of a clinical study published in the European Respiratory Journal demonstrated that lung cancer characteristics may be recognized with precision using Cellvizio®'s AQ-Flex™ 19

confocal miniprobe through thin needles.

Held 17 presentations supporting Cellvizio® during the Digestive Disease Week® (DDW) Conference in San Diego in the United States. These presentations address Barrett's esophagus, inflammatory bowel disease (IBD), food allergies, pancreatic cysts and other gastrointestinal diseases. The studies focused on the potential impact from the use of Cellvizio® in patient treatment and improvement of results.

Three recent clinical publications have shown that Cellvizio®'s AQ-Flex™ 19 significantly improves the accuracy of diagnosis compared with the standard methods, with a positive impact on the treatment of patients suffering from pancreatic cystic lesions. These recent publications show the very high diagnostic yield of confocal endomicroscopy (84% to 91%) whilst confirming the accuracy of differentiation between mucinous and non-mucinous cysts (97% in both studies). These high diagnostic yields influenced 28% of therapeutic decisions of patients with a pancreatic cyst, allowing monitoring to be stopped in the case of 35% of patients with benign cysts and reversing the choice between monitoring and surgery in 15% of pre-cancerous lesions, thus preventing unnecessary surgery.

Participation in a Dutch consortium of molecular imaging which was awarded a grant of €5.4 million. The purpose of the MEDPHOT consortium is to develop an optical molecular imaging solution for pulmonary diseases. Molecular imaging is used to gain a better understanding of the organism's molecular and cellular processes and has the potential to transform healthcare, enabling earlier detection and personalized treatment of certain diseases.

**2020**

*New authorizations*

On March 3, 2020, Mauna Kea Technologies obtained 510(k) authorization (K193416) in the United States from the Food and Drug Administration (FDA) as well as CE marking for the new generation endomicroscopy platform Cellvizio®, developed with the company's new proprietary architecture. This is the 18th 510(k) authorization from the U.S. FDA for the pCLE/nCLE Cellvizio® platform. The new Cellvizio platform incorporates innovative modular design solutions to facilitate and better incorporate endomicroscopy in operating theaters as well as in the platforms of other manufacturers. The hardware and software for the new platform has been completely redesigned to make it future-proof in particularly to allow the integration of artificial intelligence functionalities (deep learning) to assist in the interpretation of endomicroscopic images. The new ergonomy and considerably reduced size of the new Cellvizio means it can be easily integrated in advanced navigation, robot-assisted and laparoscopic surgery systems. This new system is also capable of integrating other proprietary endomicroscopic architectures, enabling imaging on other wavelengths intended for fluorescence image-guided surgery and molecular imaging.

*Pneumonology*

As part of his collaboration with Johnson & Johnson's Lung Cancer Initiative (LCI), Dr. Christopher Manley, Director of the Department of Interventional Pulmonology and Assistant Professor of Medicine at the Fox Chase Cancer Center (FCCC) in Philadelphia, and Dr. Jouke T. Annema, Professor of Pulmonary Endoscopy at the University of Amsterdam Medical Center, obtained approval from the FCCC to initiate a pilot clinical study, combining nCLE and navigation robotic bronchoscopy, using both Cellvizio® and the Monarch™ platform from Auris Health, Inc. one of Johnson & Johnson's medical device companies, for the diagnosis of peripheral lung nodules. This study will be co-financed by Johnson & Johnson's LCI and Mauna Kea Technologies (Clinicaltrials.gov: NCT04441749). The main objective of this study is to assess the feasibility and safety of nCLE during bronchoscopy with robotic navigation in the assessment of peripheral lung lesions. This study will cover 25 patients with peripheral nodules.

*Gastroenterology*

Publication of the American Society of Gastrointestinal and Endoscopic Surgeons (ASGES) peer-reviewed study "Technology and Value Assessment" (TAVAC) on the safety and efficacy of confocal laser endomicroscopy as a diagnostic tool for the evaluation of gastrointestinal pathologies. This article, entitled "SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy", was published in the international peer-reviewed journal Surgical Endoscopy (doi.org/10.1007/s00464-020-07607-3), the official journal of SAGES.

*New funding*

On April 17, 2020, the Company obtained confirmation from the EIB that it could draw down the second instalment of €6,000 thousand pursuant to the contract. On July 8, 2020, in accordance with the loan agreement as amended on June 19, 2020, the Company received Tranche 2 for €6 million. This second tranche will bear annual interest of 3% and capitalized interest of 4% payable in 5 years with the principal. Tranche 2 is also accompanied by the issue of share subscription warrants (BSA) entitling the holder, in the event of exercise, to subscribe to a maximum of 500,000 Company shares (i.e. 1.6% of the share capital on a non-diluted basis). These BSA warrants were issued on the basis of the twenty-fourth resolution adopted by the Combined General Meeting of July 2, 2020. The exercise price of the warrants is equal to the volume weighted average of the last three trading days preceding their issue, less a 5% discount. The BSA warrants may be exercised starting from their issuance and until July 3, 2039.

On April 20, 2020, through its subsidiary Mauna Kea Inc. the Company was awarded a of €0.6

million under the Paycheck Protection Program in the United States.

On July 17, 2020, the Company announced that it had received approval from BNP Paribas and Bpifrance for a €4 million financing in the form of a Loan Guaranteed by the French Government (PGE). BNP Paribas and Bpifrance will each grant a loan of €2 million at fixed interest rates of 0.25% and 1.75% respectively. These non-dilutive loans will be 90% guaranteed by the French Government (ministerial orders of March 23 and April 17, 2020 granting the French Government's guarantee to credit institutions and financial companies, pursuant to Article 6 of Law No. 2020-289 of March 23, 2020). Each loan is for an initial term of one year. At the end of the first year, repayment of the principal due may be again deferred, at the Company's option, for a maximum 5 year term.

## 5.2 Investments

### 5.2.1 Principal investments made since 2017

| Gross investments (IFRS Standards, in €K) | 2019 financial year | 2018 Financial year | 2017 Financial year |
|---|---|---|---|
| Intangible assets | 855 | 101 | 185 |
| Property, plant, and equipment | 525 | 1,153 | 542 |
| IFRS 16 rights of use | 369 | n/a | n/a |
| Non-current financial assets | 40 | (5) | (24) |
| **TOTAL** | **1,789** | **1,249** | **703** |

***Intangible investments***

The intangible investments are primarily made up of development expenses and expenses for registering patents. Their breakdown by type is shown in Note 3 of the consolidated notes in Section 20.1of this Universal Registration Document.

The research expenses are consistently recognized as expenses. Only development costs that meet the criteria of IAS 38 are recognized as intangible assets (see Note 1.4 to the consolidated financial statements in Section 20.1of this Universal Registration Document).

In 2019, the Company capitalized the GEN III development costs because the expenses were IAS 38-eligible.

***Tangible fixed investments***

Tangible fixed investments primarily consist of industrial equipment and office and computer equipment. Their breakdown by type is shown in Note 4 of the consolidated notes in 20.1of this Universal Registration Document.

***IFRS 16 rights of use***

The Group applied IFRS 16 for the first time as of the financial year beginning on January 1, 2019, which relates to operating leases with a term of more than twelve months and whose assets have a unit value of more than USD 5,000.

This standard, which is mandatory from 2019, mainly covers real estate leases in France and the USA as well as motor vehicle leases. The impact of the first-time application of this standard on the consolidated financial statements is shown in Notes 1.1 and 4 of the consolidated notes in Section 20.1 20.1this Universal Registration Document.

***Non-current financial assets***

The non-current financial assets include only the security deposits paid according to ordinary rental agreements.

### 5.2.2 Principal investments in progress

Since December 31, 2019, the investments made have been of the same kind and order of magnitude as those mentioned above during the 2017-2019 period.

### 5.2.3 Principal investments projected

At this time, the Group is not planning to make any significant investments for the years to come for which the executive bodies of the Company have made any firm commitments.

# SECTION 6
# 6. OVERVIEW OF OPERATIONS

## 6.1 Executive summary

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer thanks to real time in vivo microscopic visualization of tissue, or "optical biopsy". The Company's flagship product, Cellvizio, has received clearance to sell for a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, South Korea as well as several Latin American countries.

The Group has designed, developed and marketed an innovative imaging platform used to view tissues at cellular level, in real time, during standard procedures. Through this set of new technologies, the microscope can be positioned in the patient's body to enable better removal of tissue or organ fragments from the patient and to increase diagnostic yield by performing biopsies on tissue with abnormalities.

The technological platform, called Cellvizio, thus positions the Group as a key player in the digital transformation of medicine and surgery. The Group's objective is therefore to develop further, from diagnostic methods of an analog paradigm, which is costly and not very efficient, to a completely digital, instant paradigm which can provide doctors and surgeons with all the power of real-time cellular visualization with the best machine *learning algorithms*.

International multicenter, randomized clinical trials have shown that Cellvizio can help physicians to characterize or detect early-stage pathologies more precisely and make immediate therapeutic decisions.

The Company mainly focuses its efforts on the American market where conditions have improved significantly, in particular due to the reimbursement of procedures in the upper digestive tract.

Furthermore, the implementation of our strategic plan will make Mauna Kea Technologies a leading player in the digital transformation of medicine and surgery, is now well underway. After successfully bringing microscopes into the patient's body, the Company is now on the verge of bringing in vivo the connected laboratory of the future, harnessing the full power of the latest artificial intelligence techniques now available in the Cloud and the advent of next-generation molecular markers.

### Marketing authorization obtained

The Company's flagship product, Cellvizio, has received marketing authorization for a wide range of applications in many countries, including the United States, Europe, Japan, China and South Korea. The Company mainly focuses its efforts on the American market where conditions have improved significantly, in particular due to the reimbursement of procedures in the upper digestive tract.

The Group has obtained fifteen 510(k) regulatory authorizations from the United States Food and Drug Administration (FDA) as well as CE marking in Europe for its use in digestive, pulmonary and urological tracts using endoscopy. In 2015 Mauna Kea Technologies also obtained CE marking for two new confocal miniprobes for laparoscopic surgery and interventional radiology, and in October 2015 and August 2017 FDA regulatory authorization in laparoscopic surgery including manual surgery and robotic-assisted surgery. In 2018, the Group obtained regulatory authorization from the Food and Drug Administration (FDA) in neurosurgery and in 2019, Mauna Kea received a new FDA 510(k) authorization in the United States for the use of the AQ-Flex 19 confocal miniprobe through the use of transbronchial needles with existing bronchoscopes and bronchoscopic accessories. This is the 16th 510(k) authorization received from the U.S. FDA for the Cellvizio® platform. Obtaining this authorization is a major regulatory milestone for Mauna Kea, particularly as it supports our market development strategy: evaluating the commercial potential of our Cellvizio technology on the international pulmonology market. The AQ-Flex™ 19 confocal miniprobe is opening up a new era in interventional pulmonology, allowing more accurate navigation in the optimal sampling area with potential for the diagnosis, evaluation and treatment of pulmonary lesions in real time.

On the basis of these two internationally recognized labels, Mauna Kea Technologies has obtained marketing authorizations in more than 40 countries on various continents (North America, Europe, Asia). The most recent authorizations were obtained in China (renewed at the end of 2015 for the new version of the Cellvizio 100 Series with AQ-Flex 19 miniprobes and extension to urology).

The Company has obtained dual authorization in Japan: a class 1 authorization for the use of Cellvizio technology, and a class 2 (NINSHO) authorization for the endoscopic use of confocal miniprobes. They both concern all the current clinical indications covered by Cellvizio, except laparoscopy and interventional radiology: gastroenterology, including the AQ-Flex 19 miniprobe for pancreatic cysts, urology and pulmonology.

Since the beginning of 2019, the Company decided to limit the number of countries in which it maintains marketing authorizations, in order to limit itself to the most promising markets and thus optimize its financial resources.

Unless stated otherwise, the Company holds marketing authorizations for its products in all of the following countries: Belarus, China, South Korea, Ecuador, Europe (Bosnia, Bulgaria, Croatia, France, Greece, Italy, the Baltic Countries, Poland, Czech Republic, Romania, Scandinavia, Serbia), Hong Kong, Israel, Japan, Mexico, Peru, Russia, Singapore, Taiwan, Turkey, USA.

Below is a summary of the indications we cover, the confocal miniprobes suitable for these indications, the geographic areas in which we can market them and where we have secured reimbursement codes.

| Route of access | Indications | Interventions | Products | Geographic marketing areas (1) (2) | Geographic areas where repayment rights have been secured |
|---|---|---|---|---|---|
| Endoluminal | Digestive endoscopy | Biliopancreatic interventions | AQ-Flex 19 | All countries except South Korea | USA: published rates including needle-based access to the pancreas |
| | | | CholangioFlex | All countries | Croatia: official rates |
| | | Endoluminal interventions | ColoFlex UHD | All countries | Croatia: official rates |
| | | | GastroFlex UHD | All countries | USA: rates published for the upper gastrointestinal tract<br>France: official rates for Barrett's esophagus<br>Croatia: official rates |
| | Bronchoscopy | Pneumological interventions | AlveoFlex<br>AQ-Flex 19 | Europe + United States | Croatia: official rates |
| | Urology | Urological interventions | CystoFlex F | All countries except Singapore & Taiwan | Croatia: official rates |
| | | | UroFlex B | | |
| | | | CystoFlex UHD R | All countries except Israel, China, Korea, Taiwan | Croatia: official rates |
| Surgery | Digestive surgery | Anti-reflux surgery | GastroFlex UHD | All countries | - |
| | Laparoscopic surgery | Oncological surgery | CelioFlex UHD 5 | Europe + HK + USA | - |
| | | Urology surgery | CelioFlex UHD 5 | Europe + HK + USA | - |
| | | Other surgery | CelioFlex UHD 5 | Europe + HK + USA | - |
| | | Robotic surgery | CelioFlex UHD 5 | Europe + HK + USA | |
| | Neuro-surgery | Neurosurgery | CranioFlex | USA only | - |
| Others | Interventional radiology | Interventional radiology | AQ-Flex IR | Europe + HK + USA | - |
| | | Biomolecular imaging | *In progress* | *In progress* | - |

(1) Unless stated otherwise, the Company holds the marketing authorizations for its products in all of the following countries: Belarus, China, South Korea, Ecuador, Europe (Belgium, Bosnia, Bulgaria, Croatia, France, Finland, Greece, Hungary, Italy, Iceland, Latvia, Lithuania, the Baltic Countries, Poland, Norway, Czech Republic, Romania, Scandinavia, Serbia, Slovakia, Sweden, Switzerland), Hong Kong, Israel, Japan, Mexico, Peru, Russia, Singapore, Taiwan, Thailand, Turkey, USA, Venezuela, Yemen.
(2) Authorizations are in the process of being obtained for all indications/products in Oman

### Cellvizio, a breakthrough technological innovation

Cellvizio is the world's smallest microscope, capable of producing in real time (9 to 12 images per second) microscopic images of the inside of the human body with exceptional stability. The images are magnified up to 1,000 times more than a traditional camera. They are obtained by pressure of the Cellvizio miniprobe on the wall of the mucosa or target organ. The process is minimally invasive and perfectly repeatable.

To date, the Company holds 248 patents which protect its technologies and methods (please refer to Section 11.2of this Universal Registration Document).

### Cellvizio, a benefit for patients, physicians and health systems

Cellvizio is designed to help physicians reduce uncertainty in their diagnosis, provide better treatment for patients and reduce hospital costs.

Cellvizio provides physicians with cellular information, in vivo, in real time and during procedures. This information is obtained in a minimally invasive way and therefore does not damage the patient's tissues. Cellvizio design was focused on requiring minimal changes to existing practices. With this in mind, a range of probes has been developed that are compatible with existing practices. For example, in the digestive endoscopy field, Miniprobes for this type of application are compatible with almost all endoscopes on the market, and integrate naturally as an endoscopic tool. Cellvizio makes it possible to improve practices without radically changing them.

Cellvizio's medical benefit has been proven by many clinical trials concerning each of the indications in which it is routinely used today.

For patients, the benefit is significant at several levels. Apart from not having to wait for the results of a physical biopsy, which can sometimes take several weeks, the process is non-invasive and can be replicated because it does not destroy the areas it inspects, and is painless. Above all, it can be used for faster characterization of precancerous and cancerous lesions.

For the health system, an optical biopsy is used to reduce the number of useless physical biopsies, since the great majority of physical biopsies are found to be negative (prostate:75%[2], Barrett's esophagus: 58%[3] for example), and reduce the number of endoscopic procedures by providing better characterization of precancerous or cancerous lesions. Cellvizio also avoids unnecessary surgery, particularly of the pancreas. (Please refer to Section "Products and clinical validation")

### Cellvizio, a multiple-indication platform

Cellvizio is designed as a platform potentially capable of bringing solutions to a large number of medical and surgical fields in which tissue characterization is required. These include gastroenterology, urology, interventional pulmonology, and surgery. With the recent advent of its new extremely miniaturized (diameter < 1 mm) miniprobe that is able to penetrate a puncture needle, Cellvizio can now access inside organs of the human body and this opens up new possibilities of improved diagnosis for very important pathologies such as pancreatic cancer or lung cancer.

Cellvizio can be used in gastroenterology, pulmonology or urology, where only miniprobes are specific to each indication. There is a miniprobe for every indication, which, depending on the model, can be reused 10 or 20 times (see Section 6.3.3Products and clinical validation").

### A protected ownership innovation

As of December 31, 2019, the Mauna Kea Technologies patents portfolio included 248 national and international patents granted. This policy of innovation and of protecting its intellectual property constitutes a significant barrier to entry for possible competitors. The Company continues to invest in R&D and will continue to maintain a dynamic policy of patent filings (Please refer to Section "Innovation, patents, licenses, brands and domain names").

### Very rich and statistically significant clinical validation

Establishing a breakthrough technology in the medical world today first requires having scientific and medical proof of the proposed innovation's contribution.

[2]Presence Of High-risk Prostate Cancer Can Be Predicted Without A Biopsy, New Study Says. ScienceDaily. ScienceDaily, May 22, 2005.

[3]Bertani H. et al. Improved Detection of Incident Dysplasia by probe-based confocal laser endomicroscopy in a Barrett's esophagus Surveillance Program. Dig Dis Sci 2013; 58(1):188-93.

A vast program of international multicenter clinical trials has been undertaken since 2005 on applications relating to the digestive tract, pulmonology and urology. All the studies finalized to date have provided conclusive results as to the Cellvizio's contribution in relation to traditional endoscopies, in particular as to the quality of the diagnosis it procures.

There are more than 1000 published references for endomicroscopy in the PubMed database, based on the key word "endomicroscopy".

The results of the Company's clinical studies program are outlined in 6.3.3of this Universal Registration Document.

As an example, in 2019, the team of professor Pr. J. T. Annema, M.D. Ph.D., head of pulmonology department at Amsterdam University Medical Centers, has demonstrated, for the first time, that imaging and identifying benign and malignant cellular structures within pulmonary nodules and lymph nodes using needle-based confocal laser endomicroscopy, was not only possible but could also be reproduced in a presentation at the ERS (European Respiratory Society) Congress held in Paris in September 2018. The availability of nCLE for lungs clearly has the potential to have a major accuracy impact on the diagnosis of peripheral nodules, one of the biggest challenges in the fight against lung cancer. An article "Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer" was published in the European Respiratory Journal (2019, DOI: 10.1183/13993003.01520-2018) in 2019. The use of needle-based endomicroscopic imaging produces accurate results on the nature of pulmonary lesions and metastatic lymph nodes according to the team of Pr. J. T. Annema, professor of pulmonary endoscopy, Amsterdam University Medical Center. In a well-designed clinical trial, it was shown that nCLE can be used to detect pulmonary tumors and metastatic lymph nodes with an 89% accuracy rate with significant intra- and inter-observer reliability. These promising findings confirm the fact that nCLE could be significant in complementing navigational bronchoscopy for the purposes of targeting and identifying pulmonary tumors in real time. It is a major publication which further supports new market opportunities in interventional pulmonology for Mauna Kea. Indeed, it shows that the use of our needle-based endomicroscopy platform is opening up a new era in interventional pulmonology, allowing more accurate navigation in the optimal sampling area with potential for the diagnosis, evaluation and treatment of pulmonary lesions in real time. Indeed, existing navigation systems offer advanced and minimally invasive access to peripheral nodules but have limited means of viewing directly outside the respiratory tract. Cellvizio, with the AQ-Flex™ 19 confocal miniprobe, can now be used through the operating channel of existing navigation systems to offer a direct "needle-based" view of the inside of peripheral lesions. Cellvizio is the leading endomicroscopic device on the market and can be integrated into robot-assisted bronchoscopic navigation platforms. As such, the approval of needle-based probes for bronchial applications is a critical milestone in continuing the exploration of possible indications for the Cellvizio technology in a field at the cutting edge of medical research.

### Repayment

In the United States, in March 2012, the Group obtained the creation of three new category 1 CPT® codes for the upper digestive tract and for interpreting images obtained with endomicroscopy. Two of these codes are available to gastroenterologists, the third code was created for use by histopathologists. In early 2016, the American Medical Association (AMA) and professional societies in gastroenterology clarified the coverage of needle-based Confocal Laser Endomicroscopy procedures in pancreatic cysts and masses (nCLE) by assigning one of the two codes covering intervention in the upper gastrointestinal tract. In March 2015, the AMA assigned a new CPT code for use in endoscopic retrograde cholangio-pancreatography (ERCP), allowing practitioners to diagnose biliary tract pathologies, notably strictures and cancers. This temporary code does not yet give rise to reimbursement.

It is essential to understand the following points to assess the importance of reimbursement in the United States:

- CPT codes are used for out-patient procedures and therefore do not apply to surgical procedures requiring hospitalization for one night or more;
- obtaining a CPT code is one of the three stages in the reimbursement of a procedure. A rate also needs to be obtained, as well as payment by government insurers (including Medicare and Medicaid) and private insurers;
- it is very difficult to obtain a CPT code, but obtaining its payment by insurers, particularly private insurers, is even harder.

Mauna Kea Technologies has managed to complete most of these three stages: it has secured several repayment codes, obtained a rate and arranged complete national medical coverage by Medicare/Medicaid and partial coverage by private insurers. The Company has changed its mode of attack for private insurers and began to see very good results in the last few months of 2015. It intends to continue this approach in order to obtain not only local cover, but also national cover by one of the large private insurers. The success of these initiatives is a key factor for success for the faster development of applications for gastroenterology. The use of Cellvizio® in Barrett's esophagus and in the treatment of patients suffering from gastroesophageal reflux was recommended by several respected learned societies in this field, including the American Gastroenterological Association (AGA), the American Society of General Surgeons (ASGS) and American Foregut Society (AFS). The College of American Pathologists (CAP) has also started to recognize technology by creating for example an in vivo microscopy (IVM) division.

For applications other than gastroenterology, the need to obtain a code will depend on the nature of the procedure, whether it is an out-patient procedure or not. The Company is now developing a certain number of applications which will not be practiced as out-patient procedures and thus will not require new CPT codes.

In Germany, the German Institute for Medical Documentation and Information (DIMDI) has assigned an OPS code to confocal endomicroscopy for its applications in the gastrointestinal tract. It appeared in the final 2014 list of OPS codes (Operationen- und Prozedurenschlüssel). The allocation and implementation of this code allows the German health authorities to measure the volumes

of procedures as well as the related costs of treatment, in order to propose a reimbursement rate. Reimbursement is also a key factor for commercial success in Germany. An experiment is currently underway for patients suffering from food allergies and irritable bowel syndrome.

In France, the French National Authority for Health (HAS) approved the use of Cellvizio® in mapping Barrett's esophagus in late 2014. In 2019, in light of the technological evaluation report, the French National Association of Health Insurance Funds (UNCAM) decided to create the procedure corresponding to the medical nomenclature, namely "Esophageal endoscopy with biopsy guided by confocal laser endomicroscopy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy". The tariffs reimbursed are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for anesthesia (Activity 4).

In September 2015, the HAS rejected the use of Cellvizio® for the characterization of biliary tract strictures. In the first quarter of 2017, the HAS concluded its review of the Group's last application, filed in 2010, to use Cellvizio® in the colon. The Group is now looking at submitting an application for the use of Cellvizio® in the pancreas.

Finally, since 2017, the Croatian Health Insurance Fund (HZZO), which manages the universal medical protection system in Croatia for approximately 4.2 million people, reimburses a series of procedures using Cellvizio®.

Summary of reimbursements requested/obtained :

| Country | Indication | Product | Competent authority | Year of submission | Description | Pricing |
|---|---|---|---|---|---|---|
| United States | Upper gastrointestinal tract, including access to the pancreas by fine needle | GastroFlex | American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS) | 2012 | Reimbursement code CPT 43206 (esophagus). Esophagoscopy with optical endomicroscopy. Came into force on 01 January 2013. | 1,483 USD for hospitals, 642 USD for ambulatory surgery center and 141 USD for physicians (applicable rates in 2019 disclosed). |
| | | GastroFlex / AQ-Flex | American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS) | 2012 | Reimbursement code CPT 43252 (upper gastrointestinal tract). Esophagogastroduodenoscopy with optical endomicroscopy. Came into force on 01 January 2013. | 2,825 USD for hospitals , 1,245 USD for ambulatory surgery center and 178 USD for physicians (applicable rates in 2019 disclosed). |
| | | - | American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS) | 2012 | Reimbursement code CPT 88375 for optical endomicroscopic image(s), interpretation and report. Came into force on 01 Janvier 2013. | 51 USD for physicians (2019) |
| | Biliary ducts (ERCP) | CholangioFlex | American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS) | 2014 | Reimbursement code CPT 039X7T. Biliary ducts. Endoscopic retrograde cholangiopancreatography (ERCP) with optical endomicroscopy. Came into force on 01 January 2016. Renewed for 5 years | Based on published rates. |
| France | Mapping of Barrett's esophagus | GastroFlex | French National Authority for Health (HAS) / Health Insurance Fund National Union (UNCAM) | 2010 | Positive appraisal from the HAS to obtain reimbursement of the medical procedure in the mapping of Barrett's esophagus (17 September 2014). | By decision of the UNCAM (Paril 18th, 2019), the esophageal endoscopy procedure with biopsy guided by confocal laser endomicroscopy is created at the CCAM and priced at €150 for the examination and €69 for anesthesia. |
| | Surveillance of scarred polyps in the colon after resection | ColoFlex | French National Authority for Health (HAS) / Health Insurance Fund National Union (UNCAM) | 2010 | No opinion will be released. This assessment has been removed from the HAS Work Program (Q1-2017). | N/A |
| | Characterization of biliary strictures | CholangioFlex | French National Authority for Health (HAS) / Health Insurance Fund National Union (UNCAM) | 2010 | Negative appraisal from the HAS to obtain reimbursement of the medical procedure (22 July 2015). Additional data are needed to provide evidence of the clinical utility of endomicroscopy in this indication. | N/A |
| Germany | Confocal endomicroscopy in the digestive tract | GastroFlex / CholangioFlex / ColoFlex | German Institute of Medical Documentation and Information (DIMDI) | 2013 | Code OPS 3-301 added in the medical nomenclature to report any endomicroscopy procedure in the digestive tract, including the biliary or pancreatic ducts. Came into force on 01 January 2014. | Insufficient volume of procedures for pricing and/or G-DRG reimbursement rates (InEK). Private hospitalization under study for allergies associated with irritable bowel syndrome |
| United Kingdom | Needle-based confocal laser endomicroscopy for characterising pancreatic cysts | AQ-Flex | National Institute for Health and Care Excellence (NICE) | 2015 | Negative appraisal from the NICE-MTEP (30 November 2015). Additional data are needed to provide evidence of the clinical utility of endomicroscopy in this indication. Publication of a technology assessment report (MIB) on 26 June 2016. | N/A |
| China | Endomicroscopy | GastroFlex / CholangioFlex / ColoFlex / AQ-Flex | Chinese Ministry of Health | 2016 | Pricing was obtained in several regions allowing hospitals to bill patients for the procedures. | Tariffs vary according to the regions. |
| Croatia | Confocal endomicroscopy | GastroFlex / CholangioFlex / ColoFlex / AlveoFlex / UroFlex / CystoFlex | Croatian Health Insurance Fund | 2017 | Cellvizio procedures are now covered for patients affected by gastrointestinal, biliopancreatic, respiratory and urinary diseases in the Clinical Hospital Centers. | Additional payments ranging from €250 to €800 according to the indication of the procedures. |
| South Korea | Confocal endomicroscopy of the esophagus, stomach and bile ducts | GastroFlex / CholangioFlex | Korean Health Insurance Review and Assessment Service (HIRA) | 2018 | Files submitted to request reimbursement with specific codes | The decision will be made public by the Ministry of Health and Social Protection (MoHW) in the coming months |

The United States, France and Croatia are the only countries where the Group today has reimbursement rates applicable at the national level.

### Installed base of 673 systems sold

The Company chose rapid internationalization at the start of the marketing phase. As of the date of this URD, the Group has an installed base of 673 units (compared to 631 at the end of financial year 2018) mainly resulting from equipment sales and, to a far lesser extent, the provision of equipment (fewer than 80 units).

The installed base of more than 673 units is well spread across several continents, the Americas region, the EMEA region and the Asia Pacific region (APAC).

Over the financial year 2019, total Cellvizio System sales fell 4% year-on-year to reach 25 in 2019, versus 26 for the same period last year. New system placements within the "pay-per-use" program accounted for 40% of total deliveries in 2019, compared to 68% for the same period last year.

### Size of market

The number of facilities with endoscopy rooms is estimated at around 70,000 throughout the world, including 14,700 in the United States, 15,000 in Europe and more than 40,000 in Asia (see Section 6.4 6.4relating to the market).

In the United States, it is estimated that more than 3,400 establishments (Community hospitals and ASC) meet these criteria.

More specifically, the Group currently targets 1,100 hospital centers (1,500 physicians) in the United States specializing in digestive endoscopy, whether community hospitals with a very high level of activity around gastroesophageal reflux disease (GERD) or Ambulatory Surgical Centers (ASCs) that treat a very large number of these patients, i.e. a recurring market of more than $200 million annually.

### The Group's commercial strategy

The Company continues to rely on two distinct sales channels: Direct sales through its teams in Europe and the United States and indirect sales through a network of distributors such as Youhe Shanghai, for gastroenterology and pneumonology applications in China.

In the United States, the Company is responsible for marketing in the field of gastroenterology, its historical activity that generates a majority of its revenues, with a direct sales force. Recent progress made in the US in terms of repayment (see Section 6.3.4.), acknowledgment 6.3.4professional associations (the American Gastroenterological Association, which has 18,000 members, has acknowledged the interest of endomicroscopy and has considered its use appropriate as a replacement for random biopsy procedures in the esophagus) and of use of installed systems are all advantages to continue commercial development.

The Company's economic model is currently based, outside the United States, on the sale of equipment (or systems), on the sale of consumables (called miniprobes) which can be used a limited number of times, and on the sale of services.

In the United States, since 2017, the Company started offering its US clients a program to use of Cellvizio systems. This new commercial offer, called “Pay per use” or payment per procedure, which is targeting community hospitals as well as ambulatory surgical centers, means that clients can adopt endomicroscopy with no initial investment.

The program has been made possible by the new American reimbursement rates, which make the use of endomicroscopy a highly cost-effective clinical practice. for hospitals Payment per procedure revenues invoiced by the Company are recognized in “consumables” revenues and the systems made available are capitalized and amortized in property, plant and equipment. At December 31, 2019, this item represented €1,113 thousand.

At the end of December 2019, the U.S. sales team had 21 members. The team is composed of two regional sales managers who oversee twelve sales managers and six clinical support managers. These sales teams are managed by a commercial director.

Lastly, in China, development is led by a Business Manager assisted by a head of clinical and technical activities since April 2018.

Lastly, in the EMEA region, the commercial team was comprised of five persons:

- a sales manager who covers pre-clinical and clinical sales over the northern half of France, Benelux and England;
- a sales manager who covers the southern half of France and Southern Europe;
- a sales manager in Germany;
- a technical and clinical control manager for the German market;
- The rest of Europe, the APAC countries and the countries of Latin America are directly managed by the Vice President of International Sales.

Overall, at the end of 2019, the Group had a sales force of 26 people.

### Conclusion: establish ourselves as the leader in in vivo microscopic imaging

There is no lack of clinical proof regarding the demonstrated contribution of microscopic real-time imaging in vivo. We have now been able to prove that it is possible to obtain reimbursement of these procedures in our priority market, the United States.

We are convinced that the entry of the microscope into the human body marks the advent of a new era of early diagnosis of cancers and other pathologies. Mauna Kea Technologies intends to continue to pursue an ambitious strategy to impose digital optical biopsy as a standard of care.

The Cellvizio value proposal can be applied to many medical sectors in which biopsies are performed. Today the Group continues its commercial strategy in the field of gastroenterology in the United States mainly and is actively studying new applications that will lead to significant market developments, particularly in pneumological interventions.

At the same time, the Research and Development team is continuing its efforts to improve its products and adapt them to other specialties as appropriate. This includes technical improvements in both software and hardware, and has led to applications for

regulatory authorizations in Europe and the United States in late 2019 for the latest-generation imaging platform, which will be marketed in 2020.

### Highlights of 2019 in the Company's business

**Reimbursement obtained in France**

From mid-July 2019, reimbursement coverage of confocal laser endomicroscopy, specifically for Barrett's esophagus, through the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM). The French National Association of Health Insurance Funds (UNCAM) created the following procedure, in sub-paragraph "07.01.09.01 - Endoscopy of the salivary glands and digestive tract" of Book II of the Social Security Code: "Esophageal endoscopy with biopsy guided by confocal laser endomicroscopy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy". This decision on April 18, 2019 of UNCAM related to the list of procedures and services covered by health insurance, published in the Official Journal of the French Republic on June 14. Accessible on https://www.legifrance.gouv.fr.

**Clinical results and conferences – the value of optical biopsy**

In February 2019, publication of a new 510(k) authorization from the U.S. Food and Drug Administration (FDA) for the use of the AQ-Flex™ 19 confocal miniprobe through trans-bronchial needles with bronchoscopes and existing bronchoscopy accessories. This is the 16th 510(k) authorization received from the U.S. FDA for the Cellvizio® platform.

In May 2019, publication of a prospective study (ClinicalTrials.gov Identifier: NCT02689050) demonstrating Cellvizio's potential as a diagnostic and evaluation aid in lung cancers. The results of a clinical study published in the European Respiratory Journal demonstrated that lung cancer characteristics may be recognized with precision using Cellvizio®'s AQ-Flex™ 19 confocal miniprobe through thin needles.

In May 2019, held 17 presentations supporting Cellvizio® during the Digestive Disease Week® (DDW) Conference in San Diego in the United States. These presentations address Barrett's esophagus, inflammatory bowel disease (IBD), food allergies, pancreatic cysts and other gastrointestinal diseases. The studies chosen focused on the potential impact from the use of Cellvizio® in patient treatment and improvement of results.

## 6.2 Our Technology

### 6.2.1 Innovation strategy

**A High Capacity For Innovation**

**Technological expertise oriented towards excellence and feasibility**

Any innovation starts with an analysis of applicational needs, and concerning medical devices, clinical need analysis and its constraints related to medical practices.

Mauna Kea Technologies' strength has always been to consider that the most effective solution for designing new equipment is to start from a blank slate and to rethink the concept entirely before modeling it.

Building on this approach, in late 2003, the first Cellvizio came to be after a team of experts working within the context of an iterative process, was able to meet challenges as varied as:

- the design of a "plug and play" high-resolution confocal microscope, i.e. requiring no adjustment at its installation or during use;
- extreme miniaturization of this microscope and its lenses, the miniprobes;
- optimized image processing to make up for the physical limits of the optical components;
- the high ability to be integrated into standard equipment;
- each component designed so as to make future manufacture as easy as possible.

The quality of the study carried out upstream of the Cellvizio's design today enables Mauna Kea Technologies to have a technical platform adaptable for multiple applications with a marginal additional research and development investment.

This approach has been reiterated over the past few years and has led to the development of the next-generation Cellvizio platform, which will enable:

- the introduction of new products and services, including AI,
- laparoscopic systems to be easily incorporated in advanced robotic navigation.

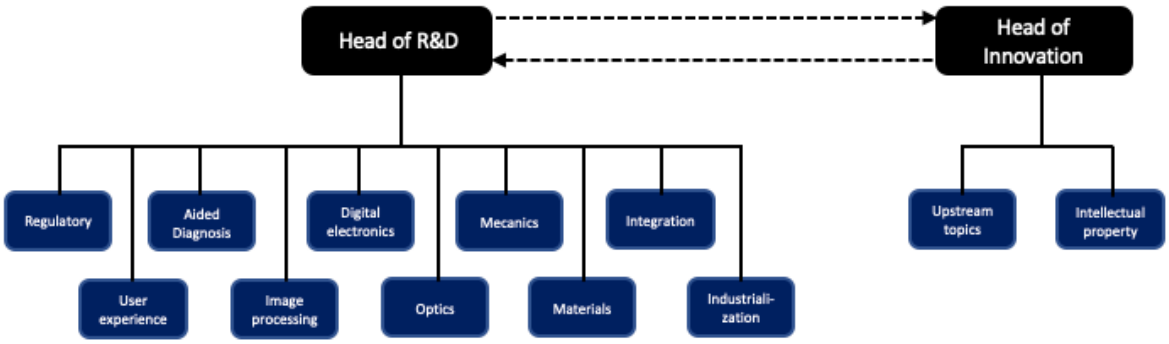
Feedback from our users has particularly been taken into account, and the system's footprint has been significantly reduced, and features a brand new user interface and an easy-to-use touch screen.

**A High-Level Multidisciplinary Team**

At the end of December 2019, the Research and Development team had 26 employees (doctors, engineers or technicians) covering the fields of expertise necessary for the development of the Group's products and technologies, namely:

- optics and optotronics;
- mathematics applied to image processing;
- digital and analog electronics;
- software development;
- systems engineering;
- micro-mechanical engineering, materials and processes for precision assembly.

The R&D team shares biological and medical knowledge regarding applications and product use with the specialists of the Clinical Affairs team and the Product Managers.




*Upstream R&D*

The Company is organized to draw on the necessary resources to directly inspire technological innovations that will enable it to expand in its market, and win new markets, by exploring solutions likely to encourage the development of innovative solutions to improve the care given to patients.

The Innovation Department provides ongoing scientific and technological oversight. Its objective is to identify and validate the ability of the technologies or components to remain at the leading edge of technology while limiting any risk of obsolescence relative to key components by identifying technical alternatives upstream.

The upstream studies arising from this monitoring are conducted by R&D department teams, either internally or through external collaborative efforts. They may constitute the preliminary phase of feasibility assessment that helps to decide whether to begin a product development project.

On the clinical level, the Company collaborates with various hospitals to assess the potential relevance and usability of the Cellvizio technology in new indications.

The upstream studies carried out in collaboration with academic laboratories are often co-funded to optimize the costs of research through grants or doctoral thesis scholarships. The first example is the "Smart Atlas" project, which allows users to search for similarities between images based on their content. This "Smart Atlas" would integrate an observation sequence history under Cellvizio and conduct an immediate comparison of reference images with images in an ongoing procedure. This study was the subject of a thesis started in 2008 in close collaboration and under the direction of Nicholas Ayache, head of the INRIA Asclepios laboratory in Sophia Antipolis. Between 2012 and 2016, it has existed in the form of an i-Lab contract between INRIA and the Company, in which two INRIA engineers who are experts in image processing are involved, in addition to the Group's engineers. Another example is the collaboration with a team from University College in London (UCL), on the increase in Cellvizio image resolution, a collaboration financed by Mauna Kea Technologie through a thesis scholarship granted to that team.

*R&D Applied To Improving Current Products And Optimizing Their Manufacture (Product Support)*

The mission of the Research and Development teams is to encourage the development of existing solutions in a continual improvement approach, while listening to internal and external clients, and carrying out the following:

- to ensure and improve product manufacturing as part of a "lean" approach. To this end, monthly meetings between the R&D department, the production team and the support team are organized;
- to develop new functions or improve the performance of existing products. The improvements are implemented after analysis of the improvement needs expressed by clients and the heads of product marketing their feasibility by the R&D teams.

A particular effort is being made relative to the approval of new methods for disinfecting or sterilizing Confocal Miniprobes so that they can be used in accordance with current hygiene regulations in healthcare facilities in the different countries in which it is marketed.

*Technical product development*

Within this mission, the Research and Development teams are working with product managers and clinical affairs managers to develop new products as part of the company's project management.

Current major projects include the new generation Cellvizio: this program which is in the process of being finalized is aimed at overhauling Mauna Kea Technologies's offering. The new Cellvizio platform incorporates innovative modular design solutions to facilitate and better incorporate endomicroscopy in operating theaters as well as in the platforms of other manufacturers. The hardware and software for the new platform has been completely redesigned to make it future-proof in particularly to allow the integration of artificial intelligence functionalities (deep learning) to assist in the interpretation of endomicroscopic images. The new ergonomy and considerably reduced size of the new Cellvizio means it can be easily integrated in advanced navigation, robot-assisted and laparoscopic surgery systems. This new system is also capable of integrating other proprietary endomicroscopic architectures, enabling imaging on other wavelengths intended for fluorescence image-guided surgery and molecular imaging.

With a redesigned user interface, Cellvizio offers smart navigation with greater efficiency and improved ergonomy. The brand new touch screen and one-handed connection to the probe mean that it is easy to install and use. Developed to bring precision imaging to a greater number of patients with 10 dedicated Confocal Miniprobes™, the new Cellvizio offers high quality imaging capability and provides clinicians with a highly effective imaging solution for theaters practicing endoscopy, minimally invasive procedures and surgery.

Development is also an opportunity for the R&D Division to rethink the solutions offered by the Company to continue to reduce manufacturing costs while improving durability. This is cross-functional work that relates as much to the system (capital equipment) as the miniprobes themselves (the consumables).

### 6.2.2 Innovation pipeline

These product development projects involve constant work on technological research for the development of new functions, in both hardware and software. This activity covers a vast area, from increasing image resolution, for instance, to assisting in its interpretation.

It is strongly based on the Company's monitoring activities, naturally, but also on the very close collaborations set up with users of Cellvizio products, in both clinical and preclinical domains.

The long-term strategy can thus be based on an excellent understanding of users' current and future needs.

**Effective project management**

The product design, modification and development activities are formalized and monitored using rigorous procedures, while preserving the agility needed for development and innovation. These activities are managed through a key quality management system within the Company.

In an extremely practical approach to project management, and depending on the nature of the project, in addition to the Research and Development, marketing and applications associates, representatives from production, the supply chain and the Regulatory Affairs teams come together far upstream in order to quickly work through technical feasibility or approval problems of the products developed.

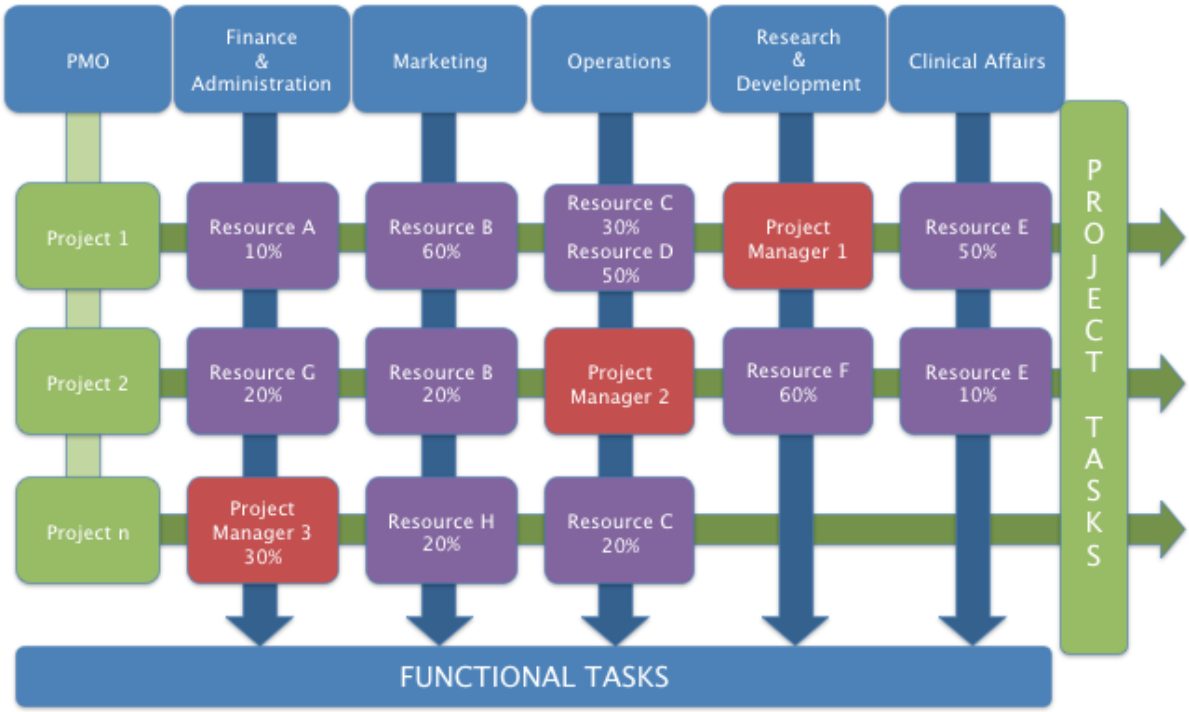
A technological and scientific "roadmap" is established and monitored regularly to ensure overall project coherence and phasing. A project is launched only once the three pillars, namely the expected objective, the calendar and the necessary resources, have been specified and validated. Project advancement is reviewed regularly at meetings during which the project manager reports to management on the different project milestones and progress of the expected deliverables.

These projects often provide an opportunity for implementing collaborative processes with industrial concerns, laboratories or academic institutions in order to optimize resources and also to add additional fields of competence.

Similarly, product developments intended for new applications in the clinical field give rise to close collaborations with physicians and/or partner laboratories.

At the beginning of 2016, the Company decided to reinforce its project procedure by creating a PMO, or Project Management Office, under the responsibility of the Operations department and led by a team of two people. This office is incorporated in an organization grid, illustrated below, in which the Company does not have project management-dedicated resources all the time. Its aim is to harmonize project management methodologies within the Company, train and provide support for project leaders, supervise project execution, particularly the allocation of resources with heads of departments, as well as coordinating internal communication and reporting on the projects to Company management.

In 2019, ten activities were managed in the form of transversal projects. Two projects were completed, one on the optimization of optical fiber manufacturing efficiency and the other on the organization's compliance with the new European data protection regulations. Four new projects were launched: three related to regulatory or customs activities and one in product development.




## 6.3 Clinical, regulatory and reimbursement validation

### 6.3.1 Clinical strategy

The team's main mission is to define and implement the Company's clinical plan. More particularly, clinical resources are dedicated to setting up and managing clinical trials of existing or new products, as well as developing medical-economic evidence concerning the use of Cellvizio, a decisive element in requests to have confocal laser endomicroscopy covered by the health authorities (public and private insurers), while clinical data are essential for the adoption by practitioners of recommendations by Learned Societies.

### 6.3.2 Functions and benefits of the technology

**The principles of optical biopsy**

Endoscopy, based on visual, minimally invasive entry into the body's natural passages, is a well- known screening and treatment method. Since nearly 90% of cancers develop in the mucosa (Source: Year 2000 Surveillance Research from the American Cancer Society), endoscopic access to these membranes, located in hollow organs like the esophagus or colon, provides a major improvement in patient comfort and diagnosis generally. If everyone aged 50 and over followed the recommendations for screening, particularly the colonoscopy, 60% of deaths due to colorectal cancer could be avoided (Source: Center for Disease Control and Prevention, 2014: http://www.cdc.gov/cancer/colorectal/pdf/no_pocket_brochure.pdf).

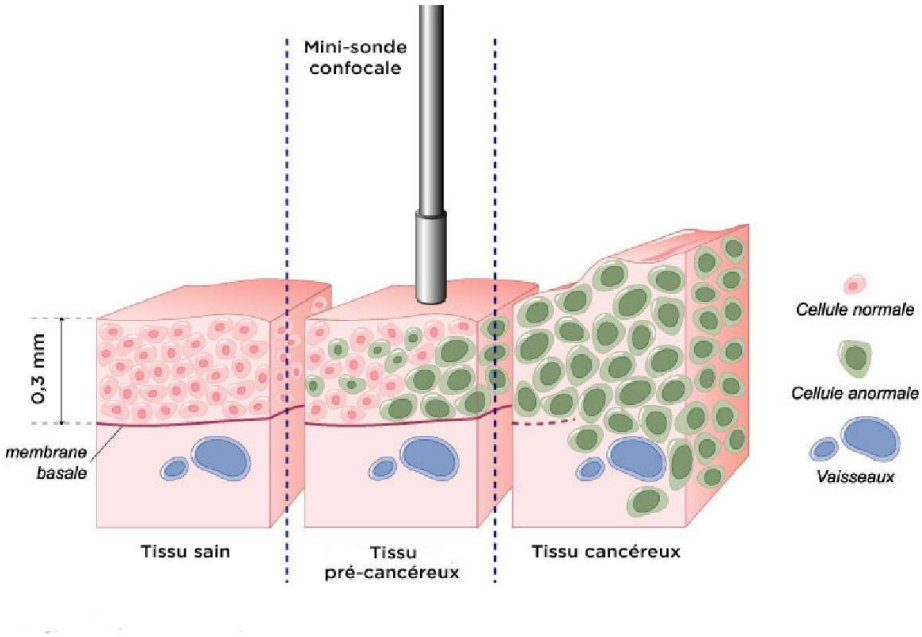



*Diagram of cancer cell progression from the mucosa to the surface (progression invisible with endoscopy) and ability of Cellvizio miniprobe to image a precancerous zone.*

Using a camera located at the end of a flexible, articulated tube - an endoscope - the physician can identify lesions from which samples (biopsies) can be taken for histological confirmation of the macroscopic diagnostic impression.

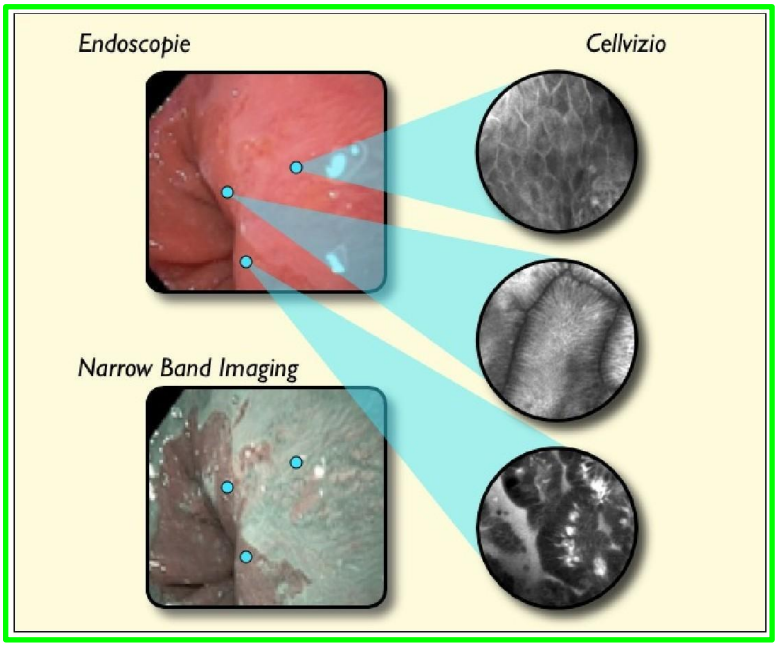
Microscopic analysis of the cellular architecture of the samples is then entrusted to the Histopathology department, which differentiates and characterizes any alterations found. This sampling and testing procedure is always conducted on dead cells over a period of time that may take weeks, so the physician is unable to intervene in real time during the endoscopic procedure. Moreover, for the biopsy itself, the physician must rely on the images received from the endoscope, so the selection of sampling zones is limited by the microscopic size of the cells and their location under the surface of tissues (esophageal, gastric, etc. mucosa), i.e. areas that cannot be accessed with a biopsy forceps. When they can be done, biopsies are therefore conducted "blind" in areas where the physician can only estimate that suspect lesions are probable. The quality of the sample is thus not always usable for diagnostic purposes, often requiring one or more additional endoscopic procedures, delaying diagnosis and therapy for diseases for which early intervention is a determining factor in recovery rates.

*Overview of a standard flexible endoscope (left) and view of the distal part with the camera, optical fiber illumination and operating channel with biopsy clamp inserted.*

Faced with this observation, over the last twenty years or so, players in the endoscopy market have improved their equipment with a view to improving the macroscopic vision of tissues. However, this progress only marginally improved the ability to locate suspicious lesions and did not enable microscopic-level access, which remained for the tissue pathologist alone.

The diagram below shows the essential difference between a standard or improved endoscope and the Cellvizio. The slide on the left shows the macroscopic vision of esophageal mucosa with standard endoscopy, corresponding to actual size x4, and on the lower left with contrast enhancement (narrow band imaging, NBI), with no change in image size. The images on the right show a real-

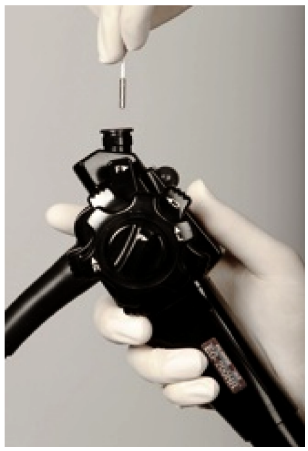
time in situ microscopic image obtained with the Cellvizio, which allows for immediate characterization. The scale is normal x1,000, corresponding to visualization at the cellular level.




**Benefits of the technology**

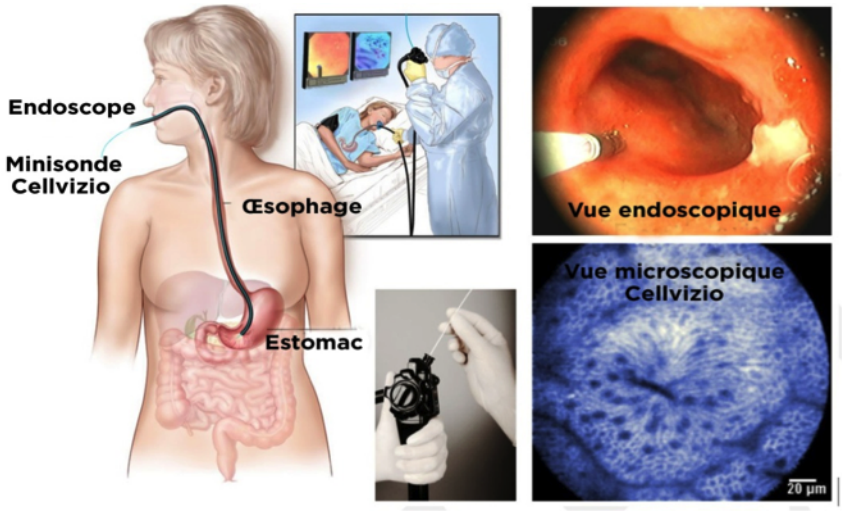
By bringing the microscope to the patient rather than taking a sample (biopsy) from the patient and putting it under a microscope, the Cellvizio combines all the key diagnostic steps in the endoscopic procedure. In fact, for the first time, the clinician has real-time relevant cellular information:

- for optimized diagnosis and better diagnostic yield than traditional biopsies;
- for places which are difficult to access, where performing a biopsy is compromised, the Cellvizio can provide key microscopic information for diagnosis;
- to decide, if necessary, to perform an immediate therapeutic endoscopic procedure, to send a patient to surgery or not, or to confirm the absence of disease and limit useless operations.



*Insertion of a confocal miniprobe into the operating channel of a standard endoscope.*

*Confocal miniprobe exiting the end of the operating channel of a standard endoscope. All endoscopes have such a channel for instrument passage.*




*Cellvizio procedure in an endoscopy room: the physician simultaneously has the endoscopic image (macroscopic, on the left of the image) and the Cellvizio image (microscopic, in the center of the image).*

Mauna Kea Technologies offers a major value proposition because it benefits all actors in the healthcare chain.

Indeed, clinical studies* performed with the Cellvizio have demonstrated the following benefits:

**For patients**

- real-time clinical information,
- a less invasive procedure than a biopsy,
- for certain indications, reduction of unjustified endoscopic and surgical procedures.

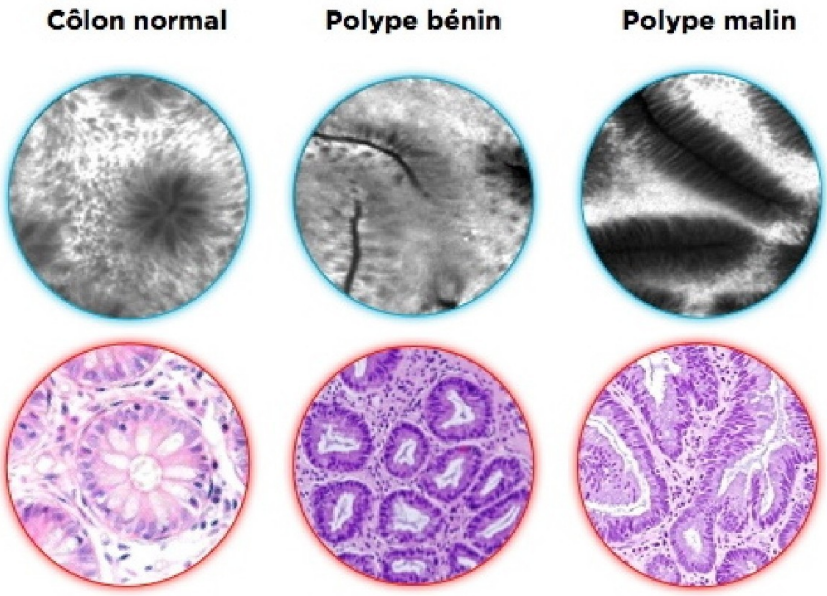
**For physicians**

- *in situ* and *in vivo* cellular-level visualization of the mucosa at suspicious sites defined using macroscopic endoscopic technologies (White light, NBI, etc.), enabling microscopic visual characterization of tissues in real time, which increases diagnostic accuracy;
- additional element for improved patient management by reinforcing the physician's role during both diagnosis and choice of treatment: the ability to both avoid useless treatments and anticipate those that are necessary;
- being at the cutting edge of technology compared with their peers;
- increased visibility for their department or healthcare facility, thus an increased number of patients treated by their department or facility.

**For healthcare facilities**

- presenting themselves as an expert center equipped with cutting edge technology,
- offering advanced endoscopy for the digestive, pulmonary and urinary systems, in laparoscopic surgery and in interventional radiology,
- attracting customers looking for better medical practices,
- optimized yield of the diagnostic treatment,
- improved therapeutic decisions,
- potential reduction in unnecessary endoscopic and surgical procedures.

Each of these points helps significantly reduce healthcare costs for public or private actors.




*Images obtained in vivo with the Cellvizio during a colonoscopy (above) compared with images obtained ex vivo in the analysis laboratory. Note the similarity between the images.*

**Current applications**

The Cellvizio potentially targets all the medical fields in which physicians need to evaluate the type of tissues to make decisions regarding their patients' treatments. These include gastroenterology, urology, pulmonology, surgery and interventional radiology.

As the Company does not have the necessary resources to pursue all of these opportunities head-on, in 2005 it decided to focus on the gastroenterology market, given the Cellvizio's contributions to various pathologies which are particularly hard to diagnose: Barrett's esophagus, precancerous lesions in the stomach, biliary strictures, colorectal polyps, chronic inflammatory intestinal diseases, and more recently, pancreatic cysts. The first sale in this field was made in 2007. The same year, the first sale of a Cellvizio dedicated to pulmonology was made.

To date, digestive pathologies accessible by endoscopy are still the indications in which Cellvizio is the most used and the most sold. The Company has obtained regulatory approvals and high level clinical evidence in other applications and is currently studying their potential. From among these, the exploration of the bronchi and targeting of peripheral nodules, potentially malignant, seems to be a very promising avenue. The applications in urology and neurosurgery are others.

### 6.3.3 Products and clinical validation

**Product description**

The Group offers two product ranges: the first range is designed for healthcare facilities (hospitals and clinics) and the second is for small animal research laboratories and is known as Cellvizio – LAB.

No matter what its application, the Cellvizio system comprises four main components:

- a central base comprising the display screen, optoelectronic Laser Scanning Unit or LSU;
- the computer processor;
- the Confocal miniprobes, specific to each indication, which are therefore the consumable components;
- the real-time image processing and display software. The extremely high quality of the images delivered by the miniprobes is one of the Group's primary areas of expertise, image processing; without this, the images captured by the tens of thousands of miniprobe fibers would simply be illegible for the physician.

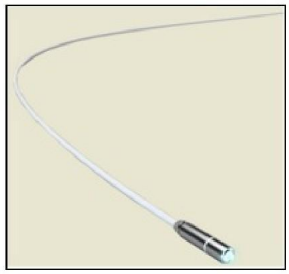
Given technical and software developments, the Cellvizio's obsolescence is reached after five to seven years. The most recent version of the Cellvizio, called Cellvizio 100, is the second generation platform and is currently marketed in most countries, in particular in Europe and the United States. The Cellvizio 100 is an easier to use system, through an improvement in the user interface, its general ergonomics and the time needed to start up the device. Progress has also been made in the quality of images obtained.

The miniprobes can be reused between 10 and 20 times and are removed with standard equipment, in the same way as endoscopic accessories. They constitute a source of recurrent revenue for the Group.

To date, the Cellvizio® is offered with various probes designed to meet the specific needs of each medical specialty:

- for digestive endoscopy applications:
  - GastroFlex UHD probe for eso-gastro-duodenoscopy (EGD),
  - CholangioFlex probe for endoscopic retrograde cholangio-pancreatography (biliary strictures),
  - ColoFlex UHD probe for colonoscopy (colorectal polyps),
  - AQ-Flex 19 probe for cytopuncture using echoendoscopy to access pancreatic cysts.
- for bronchoscopic applications:
  - AlveoFlex probe to access the pulmonary bronchi and alveoli;
  - AQ-Flex 19 probe for access to the peripheral nodules through transbronchial needles.
- for urological applications:
  - UroFlex probe for ureteroscopy (upper urinary tract),
  - CystoFlex for flexible cystoscopy (bladder),
  - CystoFlex UHD probe for rigid cystoscopy (bladder);
- for digestive surgery applications:
  - CelioFlex probe for laparoscopy (except for the reproductive organs).
- for interventional radiology applications:
  - AQ-Flex 19 IR probe.


***Unité centrale***



***Mini-sonde confocale à connecter sur l'unité de balayage***

***Example de packaging de mini-sonde***

Confocal miniprobes are made up of a bundle of several tens of thousands of optical fibers sequentially scanned by a laser beam emitted by the scanning unit. They transport the Laser beam to the area to be observed, inside human anatomic tracts. Fluorescence (exogenous or endogenous) emitted by the tissue under laser excitation is collected by the miniprobe and analyzed to compose the image of the tissue.

During use, the miniprobes must be connected to the Laser Scanning Unit and then inserted into the operating channel of the endoscope like a biopsy forceps would be, for example, to provide the in vivo fluorescence microscopic imaging during the endoscopy procedure. They are fully compatible with all the standard equipment being used in endoscopy rooms and, unlike traditional endoscopy, provide deep (up to 150 µm) observation of the mucosa, the preferred layer for locating cancerous tumors.

Apart from the hardware platform and miniprobes, Mauna Kea Technologies is also developing successive versions of its image processing software. In 2013, the Group announced the launch of EVA, "Endomicroscopy Virtual Assistant" based on version 2.2 of its software, which improves the ease of using the Cellvizio and reduces the learning curve by using new functions such as the on- board atlas of reference images, the tool for automatically selecting the most stable videos, or its connectivity with hospital patient data archiving systems. EVA is part of the service offering associated with Cellvizio, which allows users to add different

services to their equipment: preventive and corrective maintenance, loan services or replacement in the event of failure, software updates, remote support, etc.

The main benefit of the Cellvizio design, apart from being particularly adapted for easy manufacture, lies in the fact that it consists of a unique microscopy technological platform, providing guaranteed stability over several years and the fact that only the probes provide the specific link between this standard platform and the application concerned (digestive tracts, pulmonary tracts, etc.), thus enabling the platform to be used by several hospital departments or physicians.

The Cellvizio – LAB is a version of Cellvizio adapted for the needs of laboratories and research centers that conduct testing on small animals. The miniprobes used with Cellvizio – LAB are specific and lead to broader applications than the clinical version, such as neuroscience and immunology applications.

**Clinical validation**

Mauna Kea Technologies has launched an ambitious clinical trial program both directly and through industrial or academic partners. Although these studies are not part of a regulatory process for marketing authorization, they are every bit as critical. Imposing a new technology within the terms of perfectly known medical procedures mastered by health professionals (physicians and nursing staff) first means obtaining the support of opinion leaders in the field concerned. This means scientifically demonstrating the benefits of confocal laser endomicroscopy as compared to existing alternatives and distributing these results to opinion leaders and scientific societies so that they can use them to recommend this new procedure and request that it be included in their respective countries' reimbursement programs.

The key mission of the Group's Clinical Affairs department is to enter into collaborative studies with expert centers to establish the clinical validity of Cellvizio. With years of experience in international multicenter studies and randomized studies, the clinical teams move through a sequential process for each trial using the following steps:

- selection of the therapeutic intervention in accordance with the Company's development strategy;
- expected value proposition;
- once the clinical roadmap has been decided, Mauna Kea Technologies goes through a rigorous selection process to determine which hospital centers would be best positioned to collaborate with the projected study;
- definition and monitoring of study protocols;
- patient recruitment management;
- definition and monitoring of study protocols;
- data analysis;
- scientific communications and medical articles.

Numerous international multicenter clinical trials to date have shown that with Cellvizio, physicians are able to more precisely and rapidly detect or characterize early forms of diseases, thus enabling them to decide which treatments to prescribe in real time. This clinical validation is decisive. It conditions the support of many opinion leaders throughout the world and American and French scientific societies.

It consists in more than 1,000 clinical publications about confocal laser endomicroscopy in reference scientific journals and constitutes one of the Group's most important elements prior to the widespread marketing of Cellvizio for growing indications.

The majority of studies of digestive tract disease indications were part of the business strategy started by the Group in 2007 to make gastroenterology its priority market. Today, confocal laser endomicroscopy has a significant amount of clinical evidence for digestive indications, demonstrating the unrivaled accuracy of real-time tissue imaging by Cellvizio®. This level of evidence provides access to the medical-economic demonstration stage which is key for access to reimbursement in certain countries. The results detailed below include the main published clinical results for the most solicited indications.

A general review on the performance of confocal laser endomicroscopy for major indications in gastroenterology (Fugazza, Biomed Res, 2016) summarizes the state of the art from 662 publications and 102 studies. These show that the unrivaled accuracy of real-time tissue imaging by Cellvizio and similar technologies significantly alter the diagnostic conclusions of practitioners and patient management.

Confocal laser endomicroscopy can be used to significantly improve the detection of precancerous and cancerous lesions compared with conventional endoscopy and biopsy procedures for patients concerned, as well as confirming the absence of suspect lesions in healthy patients. This leads to faster and more justified intervention for patients, thus enabling them to avoid certain complex and useless procedures. The specificity of CLE exceeds 90% in almost all of the applications tested.

**EBE (Endo-brachy-esophagus)**

Pathology characterized by the development of a metaplasia in the lower esophagus, following reflux. Normal esophageal tissue is gradually replaced by abnormal, intestinal type tissue in the lower esophagus, which may develop into a form of cancer in the absence of treatment.

According to four trials concerning 242 patients, confocal laser endomicroscopy using Cellvizio detected 97% of patients suffering from EBE-type dysplasias compared with traditional endoscopy techniques, which detect 10% fewer. Moreover, the diagnostic results of this imaging technique provide the possibility of reducing the number of physical biopsies, eliminating negative samples while enabling immediate endoscopic treatment through the ability to exclude the dysplasia, with a high confidence level and a negative predictive value of 98%.

Confocal laser endomicroscopy therefore provides a valid option for monitoring patients suffering from an EBE, providing a diagnostic tool with reliable and immediate results, enabling an appropriate treatment to be provided for their needs.

In 2015, the American Gastroenterological Association (AMA) published a white paper emphasizing that it was appropriate for a medical practitioner trained in the technique to replace random biopsies with biopsies targeted by endomicroscopy. The College of American Pathologists (CAP) published a similar document. Lastly, the American Society of General Surgeons (ASGS) published a recommendation for the use of Cellvizio® for patients with gastroesophageal reflux. In 2018, the results of a study, conducted by 8 non-academic centers in the United States, were published in Surgical Endoscopy, the official journal of SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) in screening and monitoring Barrett's esophagus. The article, entitled "Real-time diagnosis of Barrett's esophagus: a prospective, multicenter study comparing confocal laser endomicroscopy with conventional histology for the identification of intestinal metaplasia in new users," highlights a much better sensitivity of confocal miniprobe endomicroscopy for the detection of Barrett's esophagus than the Seattle protocol, today considered the standard protocol. Conducted on 172 patients in 8 centers, the study achieved the following main results:

- Novice users of confocal miniprobe endomicroscopy identified more than twice as many patients with intestinal metaplasia (or Barrett's esophagus) as with the Seattle protocol: 99 vs. 46. This result is statistically significant ($p < 0.0001$);
- An expert blind review of conflicting results between Cellvizio and biopsies confirmed that Barrett's esophagus detected with Cellvizio was present in 56 of 61 patients with negative biopsies.
- No statistically significant difference between novice users of confocal miniprobe endomicroscopy and experts was shown.

**Biliary duct strictures**

This involves shrinkage of the biliary tracts preventing the bile from circulating from where it is produced, in the liver, to the gallbladder and intestines. Biliary strictures may be benign in origin or caused by a form of cancer, cholangiocarcinoma, with a pejorative prognosis and very fast evolution in the absence of early treatment.

Four trials (including the Focus trial, sponsored by the group, published in 2015) concerning an accumulated total of 252 patients, revealed that confocal miniprobe endomicroscopy detected 88% of biliary strictures of cancerous origin, against 59% using traditional methods of tissue sampling. This excellent result in favor of Cellvizio can be used to envisage a significant modification of treatment of patients suffering from this very aggressive form of cancer, by considerably reducing the number of repeated diagnostic procedures and offering a more adequate and earlier treatment.

On the other hand, a negative Cellvizio result will reassure patients with a high level of confidence and avoid repeated procedures which generate anxiety and are costly, thanks to a 78% negative predictive value versus 57% for tissue samples.

**Colorectal polyps**

Colorectal polyps are tumors which develop in the colonic and rectal mucosa. Some polyps are precancerous lesions which can lead to colorectal cancer. Early diagnosis is vital for this form of cancer, the second most deadly cancer and the third most frequent in France.

The three trials concerning 378 patients revealed that confocal laser endomicroscopy provided an accurate diagnosis for 90% of colorectal lesions against 68% using standard endoscopic procedures. Cellvizio® therefore provided better characterization of precancerous polyps and for immediate treatment of the lesions if necessary. After resection of this type of polyp, Cellvizio also facilitates characterization of the resection site to enable a second treatment in real time if necessary, a recent study having shown that this technique enables 100% of residual lesions to be correctly identified (Shahid et al., Diagnostic accuracy of probe-based confocal laser endomicroscopy in detecting residual colorectal neoplasia after EMR: a prospective study. Gastrointest Endosc. 2012 March).

Moreover, Mauna Kea Technologies promotes a strong policy of innovation, and for that, has launched a number of clinical projects to prove the utility of its new products concerning new indications. These include the characterization of pancreatic lesions, in real time, as well as pulmonary nodules. The miniprobes used in these two indications have been approved by regulatory authorities for the main markets.

**Chronic inflammatory bowel diseases**

Various studies have shown that confocal miniprobe endomicroscopy can be used on patients with inflammatory bowel disease (IBD) to go beyond clinical symptoms by assessing the state of the mucosa at the microscopic level and recommending a suitable treatment protocol. Confocal endomicroscopy by miniprobe was assessed at various stages of the disease in order to:

- identify patients with IBD[4];
- identify patients responding to initial treatment[5,6];
- make aftercare more efficient in terms of dose and duration by:
    - assessing the disease's progression and the patient's response to treatment at the cellular level[7];
    - identifying patients in remission via mucosa scarring[8],
    - anticipating relapses;
- Detect precancerous lesions and differentiate between Dysplasia Associated Lesions or Masses (DALM) and Adenoma-like Masses (ALM).[9][10]

**Cystic tumors of the pancreas: a new application with high potential**

Cavity full of pancreatic liquid developing on the pancreas, often some time after an episode of acute pancreatitis. These cysts are usually detected by accident during a scan or MRI, and some of them are potentially degenerative which can lead to pancreatic cancer.

The results of the second phase of the CONTACT study were presented at the United European Gastroenterology Week (UEGW) in October 2016, with a more complete presentation at DDW 2017. The study, involving 209 patients in five French centers, showed that needle-based endomicroscopy successfully confirmed the benign nature of undetermined pancreatic cysts with 100% specificity by confirming a superficial vascular network found only in this type of cyst and invisible to traditional imaging, identified in the first phase of this study published in 2015 in Endoscopy and in Surgical Endoscopy. This characteristic had never before been observed using other medical imaging techniques and represents a real advance in the diagnosis of benign pancreatic cysts (serous cystadenomas), thus potentially eliminating useless operations and examinations for many patients. Other characteristic signs of malignant lesions that are equally specific were presented at UEGW in 2016 and published in 2018 in the endoscopy journal (mucinous cysts and intraductal papillary mucinous tumors of the pancreas). Following these very promising results, new findings presented by Dr. Bertrand Napoléon at the United European Gastroenterology Week (UEGW) in October 2017 showed that the use of Cellvizio:

- changed 30% of diagnoses while significantly improving inter-observer agreement on diagnosis from 0.45 to 0.76 and increasing the number of diagnoses with a high degree of certainty from 57% to 79% of cases;
- changed 28% of therapeutic decisions on patients while significantly improving inter-observer agreement on these decisions from 0.36 to 0.64; avoided all forms of monitoring for 42% of patients with a benign cyst and changed the decision between monitoring and surgery for 15% of patients with precancerous lesions.

This advance will help counter the limitations inherent to taking conventional cytological samples, such as the absence of analyzable fluid.

These results represent a major advance in terms of patient treatment, avoiding useless surgery for patients with benign lesions and removing uncertainty for the practitioner making the final diagnosis.

The study also revealed how easy it is to interpret the images obtained with Cellvizio so that any endoscopist, even a novice, can achieve a reliable diagnosis.

[4]Hundorfean G. et al. Confocal Laser Endomicroscopy Provides Potential Differentiation Criteria Between Crohn's Disease and Ulcerative Colitis. Inflammatory Bowel Disease, 2012.

[5]Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012.

[6]Neumann H. et al. Assessment of Crohn's Disease Activity by Confocal Laser Endomicroscopy. Inflammatory Bowel Disease, 2012

[7]Liu J. et al. Increased Epithelial Gaps in the Small Intestines of Patients with Inflammatory Bowel Disease: Density Matters. Gastrointestinal Endoscopy, 2011.

[8]Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012

[9]Kiesslich R. et al. Chromoscopy-Guided Endomicroscopy Increases the Diagnostic Yield of Intraepithelial Neoplasia in Ulcerative Colitis. Gastroenterology, 2007

[10]De Palma G.D. In-vivo Characterization of DALM in Ulcerative Colitis with High-Resolution Probe-based Confocal Laser Endomicroscopy. World Journal of Gastroenterology, 2011.

In 2019 three publications from two prospective trials (ClinicalTrials.gov trial identifiers: NCT02516488 and CONTACTII: NCT01563133) were also published and demonstrated the positive impact of Cellvizio on the diagnosis and treatment of pancreatic cystic lesions. The articles entitled, "Diagnostic Accuracy of EUS-guided Confocal Laser Endomicroscopy for Differentiating Mucinous Mucinous from Non-Mucinous Pancreatic Cystic lesions", "EUS-guided confocal laser endomicroscopy: prediction of dysplasia in intraductal papillary mucinous neoplasms" and "Impact of needle-based confocal laser endomicroscopy on the therapeutic management of single pancreatic cystic lesions", were published in three scientific journals: Clinical Gastroenterology and Hepatology (2019, DOI: 10.1016/j.cgh.2019.06.010), Gastrointestinal Endoscopy (2019, DOI: 10.1016/j.gie.2019.09.014) and Surgical Endoscopy (2019, DOI: 10.1007/s00464-019-07062-9).

Currently, pancreatic cysts are diagnosed by testing the carcinoembryonic antigen (CEA) in the intra-cystic liquid and/or cytology, which may be subjective or difficult to interpret with over 50% of cysts unconfirmed through cytology after fine-needle aspiration. Treatment of patients with a pancreatic cyst using the standard methods also represents a challenge given the absence of optimal diagnostics and conflicting recommendations on patient treatment.

These recent publications show the very high diagnostic yield of confocal endomicroscopy (84% to 91%) whilst confirming the accuracy of differentiation between mucinous and non-mucinous cysts (97% in both studies). These high diagnostic yields influenced 28% of therapeutic decisions of patients with a pancreatic cyst, allowing monitoring to be stopped in the case of 35% of patients with benign cysts and reversing the choice between monitoring and surgery in 15% of pre-cancerous lesions, thus preventing unnecessary surgery.

**Pneumonology**

Pulmonary nodules (round or oval lesion less than 3 cm in diameter, surrounded by healthy pulmonary tissue) are usually detected accidentally, and benign, but they can also be forms of lung cancer, the most common cause of death from cancer in men and women, after breast cancer, with million deaths per year throughout the world. In 2013, Mauna Kea Technologies initiated a major trial in ten reference centers in the United States, to measure the impact of Optical Biopsy on the diagnosis of pulmonary nodules. The objective of this two-phase trial, concerning 200 patients, consists of demonstrating that Cellvizio improves the accuracy of bronchoscopies, while avoiding the need for costly and invasive clinical examinations. The Optical Biopsy will provide pulmonologists with a new diagnostic solution to improve the diagnostic yield of bronchoscopies, while providing the possibility of real-time differentiation between healthy tissue and nodular tissue.

Moreover, this same trial aims to assess confocal laser endomicroscopy's role in detecting rejection following a lung transplant. Indeed, these fragile patients must undergo a large number of bronchoscopies with tissue samples, during the weeks following the transplant, in order to detect any signs of rejection. The risk of bleeding linked to physical biopsies subjects these patients to a non-negligible risk of morbidity. In May 2017, new data demonstrating the applicability of Cellvizio in assessing acute lung rejection following transplant were presented at the American Thoracic Society's (ATS) international conference in 2017. Lead investigator Dr. Cesar A. Keller of Mayo Clinic (Jacksonville, Florida) gave an oral presentation of the clinical study called "Probe-Based Confocal Laser Endomicroscopy in the Diagnosis of Acute Lung Rejection: Results of a Prospective Multicenter Trial". The key findings of the trial were as follows:

- in a follow-up examination of 24 lung transplant patients (16 double and 8 single), Cellvizio® imaging was obtained immediately before the biopsy and the images were blindly reviewed by four pulmonologists (one Cellvizio® expert and three junior CLE readers), first independently and then after a consensus meeting;
- reproducibility was assessed by calculating the intraclass correlation coefficient (ICC) and Fleiss' kappa (k) and was found to be 0.77 and 0.39 before the consensus meeting and 0.96 and 0.77 after the consensus meeting respectively ($P<0.001$);
- The trial concluded that perivascular cellularity observed with Cellvizio was a feasible and reproducible criterion to assess acute lung rejection in *vivo* even if at this stage, it required a substantial learning curve for image interpretation.

Dr. Keller stated that probe-based endomicroscopy was a potential new tool for providing a less invasive diagnosis of acute lung rejection for transplant patients needing trans-bronchial biopsies. The results of the trial suggested that endomicroscopy could possibly spare patients unnecessary and risky invasive biopsies. He indicated his intention to continue studying this particular application of endomicroscopy in order to improve the therapeutic continuum for lung transplant patients.

This study was also published in the journal "Transplantation".11

In 2019, the team of professor Pr. J. T. Annema, M.D. Ph.D., head of pulmonology department at Amsterdam University Medical Centers, has demonstrated, for the first time, that imaging and identifying benign and malignant cellular structures within pulmonary nodules and lymph nodes using needle-based confocal laser endomicroscopy, was not only possible but could also be reproduced in a presentation at the ERS (European Respiratory Society) Congress held in Paris in September 2018. The availability of nCLE for lungs clearly has the potential to have a major accuracy impact on the diagnosis of peripheral nodules, one of the biggest challenges in the fight against lung cancer. An article "Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer" was published in the European Respiratory Journal (2019, DOI: 10.1183/13993003.01520-2018) in 2019.

[11] Transplantation. 2019 Feb;103(2):428-434. doi: 10.1097/TP.0000000000002306. Diagnosis of Acute Cellular Rejection Using Probe-based Confocal Laser Endomicroscopy in Lung Transplant Recipients: A Prospective, Multicenter Trial.Keller CA(1), Khoor A(2), Arenberg DA(3), Smith MA(4), Islam SU(5).

The use of needle-based endomicroscopic imaging produces accurate results on the nature of pulmonary lesions and metastatic lymph nodes according to the team of Pr. J. T. Annema, professor of pulmonary endoscopy, Amsterdam University Medical Center. In a well-designed clinical trial, it was shown that nCLE can be used to detect pulmonary tumors and metastatic lymph nodes with an 89% accuracy rate with significant intra- and inter-observer reliability. These promising findings confirm the fact that nCLE could be significant in complementing navigational bronchoscopy for the purposes of targeting and identifying pulmonary tumors in real time. It is a major publication which further supports new market opportunities in interventional pulmonology for Mauna Kea. Indeed, it shows that the use of our needle-based endomicroscopy platform is opening up a new era in interventional pulmonology, allowing more accurate navigation in the optimal sampling area with potential for the diagnosis, evaluation and treatment of pulmonary lesions in real time. Indeed, existing navigation systems offer advanced and minimally invasive access to peripheral nodules but have limited means of viewing directly outside the respiratory tract. Cellvizio, with the AQ-Flex™ 19 confocal miniprobe, can now be used through the operating channel of existing navigation systems to offer a direct "needle-based" view of the inside of peripheral lesions. Cellvizio is the leading endomicroscopic device on the market and can be integrated into robot-assisted bronchoscopic navigation platforms. As such, the approval of needle-based probes for bronchial applications is a critical milestone in continuing the exploration of possible indications for the Cellvizio technology in a field at the cutting edge of medical research.

In 2019, the company also sponsored a pilot clinical trial with the team of Professor Pr. J. T. Annema, M.D. Ph.D., head of the pulmonology department at Amsterdam University Medical Centers, aimed at evaluating the use of needle-based endomicroscopic imaging for peripheral pulmonary lesions. This trial will be completed in 2020 and will include between 20 and 30 patients.

Other pulmonology trials were also published in 2019 in the field of interventional pulmonology:

- Confocal laser endomicroscopy (CLE) as a guidance tool for pleural biopsies in malignant pleural mesothelioma published in the journal CHEST (Wijmans L. et al., CHEST, 2019) shows that endomicroscopy can be used to view pleural anomalies in of epithelial and sarcomatoid MPM in real time and distinguish them from pleural fibrosis. Endomicroscopy can be used as a navigational tool for biopsies in order to significantly reduce the current biopsy recurrence rate though the in-vivo identification of areas presenting with malignant cells.
- Endomicroscopy in interstitial pulmonary diseases: Descriptors and correlation with thoracic scans. A second study, published in the journal Respirology (Salaün M. et al. In vivo probe-based confocal laser endomicroscopy in chronic interstitial lung diseases (ILD): Specific descriptors and correlation with chest CT: pCLE in interstitial lung diseases. Respirology, 2019), showed that endomicroscopy can be used in-vivo for imaging the microstructure of the tissue of the distal lung during brochoscopy. Endomicroscopic conditions for the cellular infiltration of bronchiolar and alveolar areas and the alteration of the elastic acinar network can be reproduced across different observers.

**Urology**

Bladder cancer is a disease characterized by the formation of cancerous cells in bladder tissue. It is a public health problem, mainly because of the extremely high rate of recurrence (75%) which means life-long monitoring, very difficult for patients and costly for health systems.

Within the context of application to detect and treat bladder lesions, the confocal endomicroscopic technique using miniprobes provides a dynamic view of the cellular organization of the bladder wall, non-invasively, using miniprobes inserted into the cystoscope operating channel.

ECM is thus the only technique which supplies a reliable real-time diagnosis based on microscopic images, compared with simple morphological analysis based on cystoscope macroscopic images of tissue pathology obtained several days later.

To date, more than ten clinical publications concerning the use of ECM in the bladder have been published. The technical feasibility of the ECM procedure has been reported in work done by Liao et al. since 2009.

During the same year, the first results of the evaluation of technical feasibility in vivo were published in the "Journal of Urology". The study, involving 27 patients, validated the feasibility of the technique in vivo, and its ability to obtain interpretable images of the bladder urothelium and differentiate the normal mucosa from low and high grade lesions.

The first clinical trials held ex vivo demonstrated the technical feasibility of ECM in the bladder and its ability to obtain interpretable images in this indication.

A study carried out in 2011 by the same team refined the optical specifications of the miniprobe used during rigid cystoscopic procedures.

More recently, several prospective studies have led to the compilation of an atlas of ECM images in the bladder and adjacent organs and the assessment of diagnostic performance. More precisely, the atlas of ECM images obtained for a cohort of 66 patients led to the establishment of a preliminary classification of lesions observed in the bladder, kidney, prostate, urethra and ureter, including differentiation of normal tissue from inflammatory or malignant lesions.

In a study by the team of J. Liao at Stanford, California (USA), published in 2012, the diagnostic accuracy of ECM was compared with that of white light on 57 patients during TURB procedures. For low-grade lesions, the combination of white light and ECM produced a diagnostic accuracy level of 100%, with 100% sensitivity for high-grade lesions. (Source: interobserver Agreement of

Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi: 10.1089/end.2012.0549, May 2012). In addition, the team of Pr. Traxer (Tenon Hospital, Paris) published in 2015 the clinical results obtained in the upper urinary tract with Cellvizio® in a series of 11 patients (partially presented at the EAU conference in 2014). Upper urinary tract tumors represent 5% of urothelial tumors. Considering the difficulties in access, these lesions are extremely difficult to diagnose using current techniques.

The preliminary data in favor of Cellvizio is used to envisage a potential role for this technique, in both diagnosis and treatment of these lesions. ECM is also mentioned in the latest recommendations of the EAU (European Association of Urology) for its potential in diagnosing urothelial tumors.[12] Bigger trials are currently in progress to validate this preliminary data.

**Surgery**

Mauna Kea Technologies is now working to extend the scope of application of the technique, assessing its potential role in surgery, particularly minimally invasive surgery. In terms of robotic surgery, the Company has continued to expand its clinical activities as part of the BPI-funded PERSEE project. Surgery, and in particular minimally invasive surgery, is a medical field in which real-time microscopic imaging technology may have multiple applications. The Persée project, launched in 2010, is a collaborative project aimed at developing a flexible, miniature and robot-assisted endomiscroscope designed for minimally invasive exploration of the abdominal cavity in order to detect possible contraindications to excision surgery. The aim is to offer cancer patients the best therapeutic strategy between surgery, chemotherapy and radiotherapy. Multiple trials were undertaken, at the conclusion of which physicians shared their enthusiasm for and interest in the potential of these solutions which they were able to test in this first study.

The second pilot phase of the PERSEE II project launched in 2017 with the objective of confirming the findings of the initial phases of the project with other physicians at other investigational sites. These objectives will be met through a multi-center trial, using specific tools developed using the Cellvizio technology.

In 2018 researchers finalized the protocols for the two pilot multi-center trials. The protocol for the urology trial involving IMM, the Diaconesses Hospital and the Tenon Hospital was approved and the first patient was included in early 2019. The gastroenterology pilot trial was finalized and researchers obtained final approval from the French Medicines Agency, ANSM, in January 2019.

In 2019 the urology trial and the gastroenterology pilot trial were launched and continuing as planned. The objective of the trial is to reproduce the technical feasibility and safety of endomicroscopic imaging (Cellvizio® system and Persée system) in a multi-center trial and to increase the number of indications:

- Approving instrument improvements (VizioBot-P including probes, remote diagnosis, markers), image processing and the feasibility of sharing communications (voice, video) across operating theaters and anatomical pathology laboratories in a duplex or multiplex layout within the network of the various investigational sites;
- Developing interactions between investigational sites through the sharing of data/images/videos on the Cloud;
- Confirming the absence of risk associated with the procedure by comparing the learning curves of the investigational sites;
- Expanding and confirming the atlas of videos and images;

We have set target indicators and associated clinical procedures that we want to assess as part of the trial:

- Exploratory and/or resection surgery for abdomino-pelvic cancer by manual or robotic laparoscopic procedures, using indocyanine green (ICG) as the sole contrast agent, the other marker used during the single center trial. As such these trials use our F800 system at 785 nm.
- Prostatectomy and/or urology surgery:
    - Nerve protection using real-time microscopic imaging,
    - Checking of resection margins in real time at microscopic level,

Intended recruitment: at least 100 patients, and at least 10 per participating site.

Trial protocols were written and prototypes developed in 2018. Recruitment began in early 2019 as approval for two clinical trials by the ethics committees (CPPs) and French Medicines Agency (ANSM) and the signing of single contracts with the various investigatory sites took a lot longer than expected.

In 2019 an initial article, entitled "Atlas of Ex Vivo Prostate Tissue and Cancer Images Using Confocal Laser Endomicroscopy: A Project for Intraoperative Positive Surgical Margin Detection During Radical Prostatectomy" was published in the journal European Urology Focus, by both teams at the Diaconesses Hospital (urology team under Professor Guillonneau) and the Tenon Hospital (team from the anatomical pathology department under Professor Compérat). This article presents an endomicroscopic imaging atlas of prostate tissue and compares them with histological images of the corresponding tissues (see images below). This

[12] Eur Urol. 2018 Jan;73(1):111-122. doi: 10.1016/j.eururo.2017.07.036. Epub 2017 Sep 1. European Association of Urology Guidelines on Upper Urinary Tract Urothelial Carcinoma: 2017 Update. Rouprêt M(1), Babjuk M(2), Compérat E(3), Zigeuner R(4), Sylvester RJ(5), Burger M(6), Cowan NC(7), Gontero P(8), Van Rhijn BWG(9), Mostafid AH(10), Palou J(11), Shariat SF(12).

preliminary study of ex-vivo tissues confirmed that images of structures similar to the conventional histology can be produced using Cellvizio and can be used to identify the structures viewed in vivo during radical prostatectomies to ensure that resection margins are cancer-free and that nerves are not resected.

**Interventional radiology**

Feasibility studies are currently in progress in procedures concerning the liver, kidneys and lungs. The first observations were presented by Prof. Gangi of Strasbourg on the visualization of cryoablation at the Radiological Society of North America's conference (RSNA, 2015).

### 6.3.4 Marketing and reimbursement authorization

The Confocal miniprobes are classified as class II, for medical devices under special control, and benefit from a regulatory pathway for marketing (Ninsho), requiring an RCB (Registered Certification Body) approved by the Ministry of Health. The manufacturer must name the holder of the authorization (MAH or D-MAH) who will manage the records, submit a request for accreditation of a foreign manufacturer and submit the premarketing request to the RCB. The RCB issues the certificate on the basis of the evaluation of the technical dossier submitted and an audit of the manufacturer's quality system based on Japanese legal requirements relative to pharmaceutical products and medical devices, PMDL (Pharmaceutical and Medical Device Law), and prescription No. 169 which defines the relative requirements of the quality management audit system similar to standard ISO 13485.

In April 2014, the Company obtained dual class I and class II authorization in Japan for all current Cellvizio applications, namely gastroenterology, urology, and pulmonology.

In 2015, the Company obtained an extension of the marketing authorizations for the AQ-Flex 19 miniprobe used to observe pancreatic cysts.

**Summary of existing marketing authorizations (✓ ) and those in the process of being obtained (standby)**

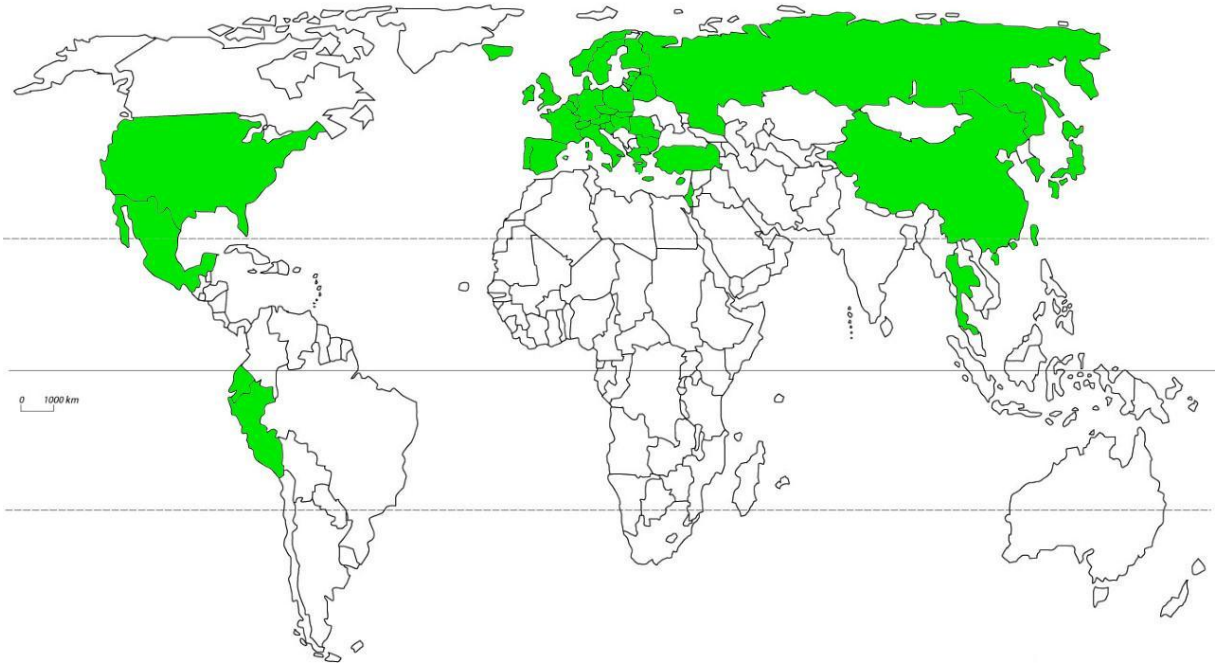
| | Systèmes Cellvizio (1) | | Bronchoscopie | | Endoscopie Digestive | | | | Urologie | | | Radiologie Interventionnelle | Chirurgie Laparoscopie | Neuro-chirurgie |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | | Int. Pneumo. | | Interventions endoluminales | | Interventions bilio-pancréatiques | | Interventions urologiques | | | Radio Int. | Chirurgie Laparoscopie | Chirurgie |
| | F400 | F800 | AlveoFlex | AQ-Flex | GastroFlex | ColoFlex | Cholangio-Flex | AQ-Flex | UroFlex B | CystoFlex F | CystoFlex UHD R | AQ-Flex IR | CelioFlex UHD 5 | CranioFlex |
| Europe | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Israel | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | En cours | En cours | | | |
| Russia | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| Belarus | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| Turkey | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| China | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | En cours | En cours | En cours | |
| Hong-Kong | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Japan | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| Korea | ✓ | | ✓ | En cours | ✓ | ✓ | ✓ | En cours | ✓ | | | | | |
| Singapore | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| Taiwan | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| Thailand | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| USA | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ |
| Mexico | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| Ecuador | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| Peru | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |

(1) Les Cellvizio F400 et F800 sont différenciés par les longueurs d'onde qu'ils utilisent ; le F800 n'est commercialisable qu'en EU et USA

| Légende | |
|---|---|
| ✓ | Autorisation de commercialisation demandée et obtenue |
| En cours | Autorisation de commercialisation demandée et en cours de traitement |
| | Autorisation de commercialisation non demandée |

This summary presents the marketing authorizations for all of the Company's products for the “clinical” market, intended for hospitals and clinics.

The following map summarizes the marketing authorizations obtained or in progress for Cellvizio medical devices. (in green)




**Relations with health professionals**

The Group has applied a code of ethics relative to these relations since 2009 which was reviewed and extended during 2018.

In France, relations with health professionals are governed by the provisions of Article L. 4113-6 of the public health code concerning the advantages consented to health professionals (so-called "anti- gift" law). In this respect, the Company has implemented ethics rules which meet these provisions.

Moreover, since 2013, the Company has declared the established agreements and advantages granted to health professionals in accordance with the requirements of the transparency law in France and the United States (Sunshine Act).

**Environment**

The Group has taken European environmental regulations into account (e.g. REACH, ROHS, WEEE) which aim to:

- limit waste and its hazards;
- promote reuse and recycling;
- improve conditions for disposal and control;
- limit or prohibit the use of certain materials.

These regulations and their requirements are taken into account in both product design (eco-design and limitation of certain substances for the REACH and ROHS regulations) and in their end-of-life disposal (directive 2012/19 relative to electronic and electrical waste or WEEE).

**Access to the market and reimbursement**

Processing of the medical procedure representing use of the Cellvizio® is a critical part of the widespread use of the technique. In each country, or each region, public and/or private insurers cover the reimbursement of medical procedures for their patients. Mauna Kea Technologies aims to obtain reimbursement for the Cellvizio® for its main clinical indications.

Accordingly the Reimbursement and Market Access team is working in close collaboration with Clinical & Regulatory Affairs and Marketing & Sales (plus local distributors if necessary), as well as external resources dedicated to the United States, in order to draw up and implement the plan for access to reimbursement in the most strategic countries for the Company from a sales point of view and for indications for which the Company has the most users.

Access to reimbursement generally involves creating a procedure (recognition of a new procedure and registration in the nomenclature), by obtaining cover for this procedure, and generating a tariff for it; three stages which can be carried out in parallel

or sequentially depending on the countries and insurers in question. It also requires the support of professional associations and expert contributors to the preparation of good practice recommendations.

*In the United States*

In the United States, in March 2012, the Group obtained the creation of three new category 1 CPT® codes for the upper digestive tract (esophagus, stomach, duodenum, pancreas). Two of these codes are available to gastroenterologists, the third code was created for use by histopathologists following a request from the College of American Pathologists (CAP) to interpret images obtained with confocal endomicroscopy.

In January 2013, endomicroscopy procedures using Cellvizio® in the upper gastrointestinal tract were added to the list of investigations that can be carried out at Ambulatory Surgery Centers (ASC). These centers, which specialize in outpatient care and less-invasive investigations, are equipped with the latest medical technologies and offer patients a quick and efficient same-day service.

In November 2016, the American health authorities (Centers for Medicare & Medicaid Services, CMS) published the Amounts of Medicare Fees for 2017 for Cellvizio® procedures in the upper digestive tract, which enables both the hospital and the physician to receive a partner payment from the public insurer in each state. This amount was revalued by 131%, leading to a major change for the company and its business model in the United States. It was increased slightly in 2018 and has remained the same in 2019.

In March 2015, the American Medical Association (AMA) assigned a fourth CPT code linked to the use of endomicroscopy in endoscopic retrograde cholangio-pancreatography procedures (ERCP), an application for which the results of clinical trials have been very positive and which enable practitioners to diagnose biliary duct pathologies, notably strictures and cancers. This category III entered into force in January 2016 and was renewed by the AMA for a 5 year period.

In early 2016, a new milestone was reached when the AMA and the professional associations (AGA, ACG, ASGE) defined the coverage for procedures in pancreatic cysts and masses (needle-based confocal laser endomicroscopy – nCLE) by assigning one of the CPT codes obtained and described above.

Mauna Kea Technologies has taken action to defend this existing cover and extend it to private insurers, thanks to specialized consultants. So far results have been convincing with several insurers announcing that they would pay for Cellvizio® procedures.

*In France*

A request for a procedure concerning the main digestive indications was submitted in September 2010 to the French National Authority for Health (HAS). The file's admissibility was notified in January 2011. The evaluation program for the procedure finally began at the end of 2013 and was finalized for the first indication evaluated, follow-up of endo-brachy-esophagus at the end of 2014, with a favorable HAS decision for registration of a new procedure on the list of reimbursable procedures. Thereafter, the Union of Digestive Tract Physicians approached the French national health insurance office (UNCAM) which is in charge of studying the scope of applications accepted for reimbursement and the treatment rates. In 2016, representatives from the French National Hepato-Gastroenterology Association (CNP HGE) and the French Digestive Endoscopy Society (SFED) held talks with the French Department for Healthcare Provision (DGOS) on the conditions under which said procedure would be approved and on the official rates set within health care institutions. In June 2019, UNCAM published it decision to create a new procedure corresponding to the nomenclature labelled as follows "Esophageal endoscopy with confocal laser endomicroscopy- guided biopsy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy".

In September 2015, the HAS rejected the use of Cellvizio® for the characterization of biliary tract strictures. In the first quarter of 2017, the HAS concluded its review of the Group's application to use Cellvizio® in the colon. The Group plans to submit a new application for uses in the pancreas and is checking the technical feasibility of an application.

*In Germany*

In 2013, an OPS (Operationen- und Prozedurenschlüssel) code was created to document endomicroscopy procedures in the digestive tract, and confocal endomicroscopy with Cellvizio® has been included in the final 2014 list of OPS codes for reimbursement of associated medical and surgical procedures by the German Institute for Medical Documentation and Information (DIMDI). The allocation and implementation of an OPS code allows the German authorities to measure volumes of procedures as well as the related costs of treatment.

**In Croatia**

Since June 2017 the Croatian Health Insurance Fund, which manages Croatia's universal healthcare system, has reimbursed a series of endomicroscopy procedures using Cellvizio® for patients with gastrointestinal, biliopancreatic, respiratory and urinary disorders with reimbursements ranging from €250 to €800. This new coverage shows that various national healthcare systems throughout the world are beginning to recognize the benefits of technology.

In other countries where Mauna Kea Technologies markets the Cellvizio®, efforts are underway to prepare and/or follow up on requests for coverage, particularly in the United Kingdom and South Korea. It is interesting to note that in China, there are regional codes enabling hospitals to invoice for using the Cellvizio®.

*In the United Kingdom*

In June 2016, the National Institute for Health and Care Excellence (NICE) published a technological assessment report on the use of Cellvizio® on the pancreas. No immediate recommendation is expected.

*In South Korea*

In March 2018, Cellvizio® obtained a positive assessment from the Korean National Evidence-based healthcare Collaborating Agency (NECA). Laser confocal endomicroscopy is recognized as a safe and effective method that can help identify cancerous lesions and target biopsies for patients with suspected dysplasia in the esophagus, stomach, and having stenosis of the biliary ducts. Applications have therefore been submitted to claim the rebate with specific codes. In 2019, the Korean Health Insurance Review and Assessment Service (HIRA) evaluated the clinical and medico-economic data provided. The decision will be publicized by the Ministry of Health and Social Welfare at the beginning of 2020.

## 6.4 Marketing and market

### 6.4.1 Marketing strategy and actions

Since the beginning of 2017, the Company has dedicated a significant portion of its commercial resources to the development of the gastroenterology market in the United States, which it addresses today with a dedicated sales team.

The other target market today is China, for which the company has a regional distribution partner, Youhe Medical, and dedicated resources.

The elements described below correspond to the Company's organization at the end of 2019.

**The Marketing and Product department**

With 9 employees, including 3 based in the United States and one in Asia, the Marketing department develops and implements the Group's marketing strategy.

The Marketing department is organized into several areas:

- the Product (upstream marketing);
- lead generation;
- downstream marketing;
- communication and digital marketing;
- key account management, which is dedicated to partner support and development.

**Lead generation**

Providing sales representatives with a steady stream of new and solid leads is essential to growth. This is the LeadGen team's goal, using several tools to meet its targets, such as buying databases, inbound marketing and event marketing.

**Applicational and product marketing**

The Marketing department is in charge of marketing specific to Cellvizio indications, mainly in digestive endoscopy but also in the other fields being studied.

This department acts as a relay between the Clinical Affairs department and the direct or indirect sales forces working in the field. In particular, the marketing teams are in charge of ongoing training for their sales force, deployment of new products or new offers, local communications campaigns and taking part in local events.

New product development or improvement projects are mainly initiated by product leaders in the Marketing department.

The department is responsible for monitoring the market and customers in order firstly to select the best projects in terms of return on investment and secondly to draft the corresponding functional specifications and monitor technical development efforts.

Once the products are developed, the product management team is responsible for launching them worldwide and providing backing sales support. It is also responsible for the educational and applicational part for each indication.

This includes educating new and potential users through training and educational activities to the physicians among them. The product marketing division monitors users' progress to ensure that they learn quickly.

The Group's business model is based on sales of medical equipment, the Cellvizio, and various types of limited-life miniprobes needed for Cellvizio use. The Cellvizio sales market is therefore based on the number of healthcare facilities that can use the technology, and the market for miniprobes is based on the number of procedures in which the Cellvizio will be used.

Cellvizio is used via the operating channel of most flexible endoscopes available on the market. However, the Cellvizio does not compete directly with existing product lines in the flexible endoscopy market. Rather than compete with the flexible endoscopy market, the Cellvizio complements existing devices.

**Event communication and digital marketing**

The event communication/digital marketing team has a strategic goal of increasing the visibility of the Group's product and trademarks. More specifically, communication is in charge of circulating marketing messages drawn up by the clinical and product teams, and implementing them in the form of marketing and communication media. It organizes events for prospects and customers and participation in international conferences. Its competence also extends to the digital communication platform (particularly websites) and public relations.

Media are divided into five categories:

- websites, including social networks;
- printed material;
- events;
- public relations and institutional communication;
- local communication actions for hospitals and clinics.

### 6.4.2 The hospitals and clinics market

In its current configuration, the Cellvizio is intended only for use by private hospitals and clinics that have an endoscopy room and physicians trained in the technique.

The Cellvizio market should be defined by geography, applications and products.

The current focus of the Group is on the United States and China, but commercial initiatives remain active in Europe. In application terms, commercial development is focused on gastroenterology, particularly in the field of upper digestive endoscopy. As regards products, the change in business model in the United States with the introduction of the "Pay per use" model encourages a shift in focus to the number of potential procedures, spread over a given number of hospitals and clinics.

**United States**

Mauna Kea Technologies' main target in the United States during the next few years includes community hospitals and Ambulatory Surgery Centers.

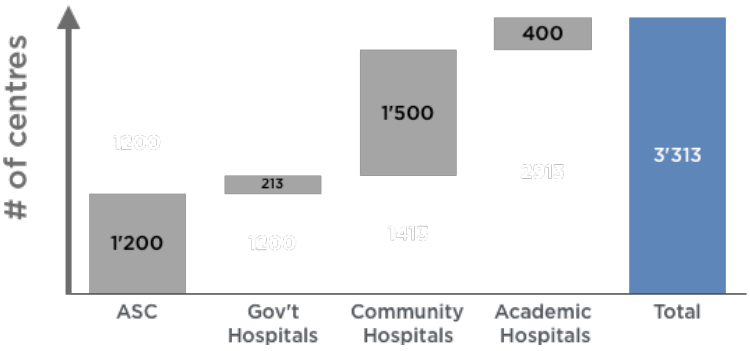
The American Hospital Association has identified 5,686 hospitals, of which 4,974 are "Community Hospitals". Community Hospitals are non-governmental hospitals that offer short-term patient management. There are also 213 governmental hospitals.

(Source: American Hospitals Association – Fast facts on US hospitals 2015, http: //www.aha.org/research/rc/stat-studies/fast-facts2015.html)

The Group currently targets 1,100 hospital centers (1,500 physicians) in the United States specializing in digestive endoscopy, whether community hospitals with a very high level of activity around gastroesophageal reflux disease (GERD) or Ambulatory Surgical Centers (ASCs) that treat a very large number of these patients, i.e., a recurring market of more than $200 million annually.

The segment of Academic Medical Centers includes 400 establishments according to the AAMC (Association of *American Medical Colleges, https: //www.aamc.org/members/coth),* and remains a secondary target.

This brings the total number of target centers for Mauna Kea Technologies in the United States to around 3,000.




**Europe**

In 2009, the European Union had more than 15,000 hospitals providing cutting-edge treatments (general medicine, surgery, obstetrics) or other activities (psychiatry, medium- or long-term stay hospitals) (*source: "Hospitals" study by Dexia in partnership with Hope, the European Hospital and Healthcare Federation, July 2008*). In terms of population, Germany and France are the two European countries with the most hospitals, close to 3,500 and 3,000 respectively.

| Country | No. of Hospitals |
|---|---|
| Germany | 3,460 |
| France | 2,890 |
| United Kingdom | 1,300 |
| Italy | 1,295 |
| Spain | 740 |
| Russia;[13] | 9,000 |
| Others | 4,615 |
| **Total** | **23,300** |

In France, the Group is targeting a market in the region of 300 hospitals and clinics that carry out interventional digestive endoscopy. This ratio applies to the remainder of the countries concerned, bringing to approximately 2,000 the number of centers potentially equipped with Cellvizio, solely for gastroenterology.

**Asia**

Japan and China are the biggest markets for Cellvizio in Asia.

The number of hospitals by country breaks down as follows:

| Country | No. of Hospitals |
|---|---|
| Japan | 7,474 |
| China | 23,170 |
| **Total** | **30,644** |

In China, there are over 1,000 hospitals in the first category, which are now the Group's preferred target.

In Japan, the Group is seeking to penetrate the academic hospital market, which covers some 200-300 hospitals.

http: //www.mhlw.go.jp/toukei/saikin/hw/iryosd/13/dl/1-1.pdf
http: //www.statista.com/statistics/279322/number-of-hospitals-in-china/
Source: WHO, European Health for All Database, 2007

**South America**

Brazil is the largest South American market with around 7,500 hospitals (70% of which are private and 30% public) and a highly developed endoscopic activity (source: International Journal for Quality in Health *Care 1999; Volume 11, Number 5: p. 437–441*).

The Group is currently focusing on the American and Chinese markets.

[13] *Source: http://dcc2.bumc.bu.edu/RussianLegalHealthReform/ProjectDocuments/n970.IIIE1.Analysis.pdf*

### 6.4.3 The potential market for probes: the number of optical biopsy procedures

Here, we concentrate mainly on digestive endoscopy indications, in which the Cellvizio is most used.

Endomicroscopy is a medical procedure separate from the endoscopy procedure during which it takes place. The Cellvizio's compatibility with the endoscopes and endoscopic tools on the market enables the miniprobe endomicroscopy (with the Cellvizio) to be performed during an endoscopy procedure in order to improve its diagnostic reliability, for example.

It is therefore possible to estimate the endomicroscopy market in number of procedures, by considering for example the indications for which the greatest number of validation works has been carried out.

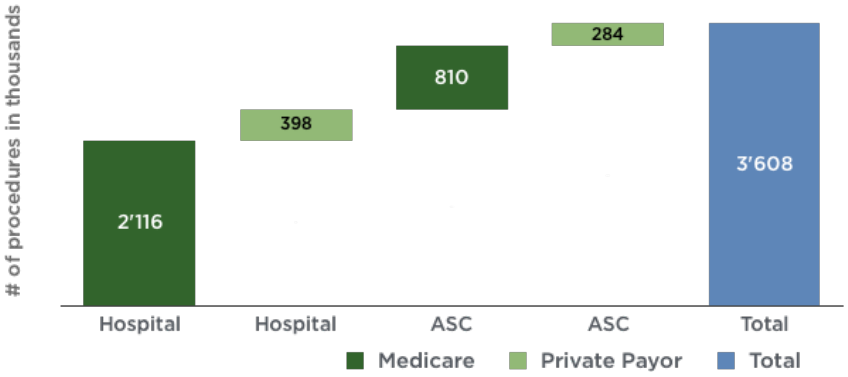
**Barrett's esophagus and gastro-esophageal reflux disease**

In the United States, it is estimated that 1.6% of the adult population has at least one symptom of Barrett' s esophagus[14], i.e. 3.6 million people, and that 20% of the adult population suffers from gastro-esophageal reflux disease.

The ability to monitor these patients endoscopically is directly linked to the detection of precancerous zones and their potential treatment.

In 2016, the American Society of General Surgeons published a major recommendation, based on these compelling arguments, for surgeons to examine their Barrett's or reflux patients using the Cellvizio prior to any surgical treatment.

The total number of upper digestive tract endoscopy procedures is close to 9 million per year in the United States. The Group's assessment shows that more than 3 million annual procedures could benefit from Cellvizio and be reimbursed. This represents potential annual recurring income of over $2 billion.




Sources: Burden of Gastrointestinal Disease in the United States: 2012 Update; Peery et al, Gastroenterology. 2012 November ; 143(5): 1179–1187.e3. doi:10.1053/j.gastro.2012.08.002. Repeated Upper Endoscopy in the Medicare Population, Pohl et al, Ann Intern Med. 2014;160:154-160. U.S. census; Medicare website.

**Indeterminate biliary strictures**

Concerning the biliary tracts, an estimated 500,000 ERCP procedures are carried out per year in the United States with an estimated 10% of these on patients with a stricture for which endomicroscopy may be prescribed, giving 50,000 procedures per year.

**Monitoring colorectal mucosectomy**

The number of colonoscopies performed per year in the U.S. is steadily increasing and is now close to 14.2 million[15]. 60% of colonoscopies are performed in hospitals as opposed to ambulatory surgical centers, which account for 40%[15] of colonoscopies. One or more polyps are found in 40% of colonoscopies and 90% of these polyps are benign. Considering only the application to detect recurrent cancers for the Cellvizio (source: multicenter study accepted for publication), the market potential is thus around 340,000 procedures (60% x 40% x 10% x 14.2) which would benefit from using Cellvizio.

[14] *Source: Gastroenterology – Dec 2005 – Ronkainen et Al*

[15] *Source : http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/*
*http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/*

**Pancreatic cysts**

From 3% to 10% of the U.S. population carries a pancreatic cyst, which represents several million patients.[16] Today, an estimated 120,000 new cysts are identified each year.[17] With a conservative estimate of 40% of patients with these cysts receiving an endoscopic diagnostic procedure justifying the use of the Cellvizio (because some cysts can be characterized as benign or malignant on the basis of endoscopic ultrasound imaging), a figure of 50,000 procedures a year in which the Cellvizio could be used to characterize a pancreatic cyst may be reached.

**Preclinical Biomedical Research and Biomolecular Imaging Markets**

Biomedical research is the primary market for the Cellvizio, with a specific product - the Cellvizio LAB - intended for endomicroscopy in small animals. The Cellvizio LAB is the premier instrument for non-invasive observation at the cellular level in laboratory animals. It is particularly adapted for observing changes in their vascular architecture or cellular morphology, and interactions between proteins or specific molecules with biological components. Alternatives to the Cellvizio LAB are instruments that cannot provide microscopic imaging, or that can offer it but in a completely invasive manner, i.e. post mortem or ex vivo.

Thanks to the Cellvizio LAB, longitudinal studies, so crucial for biological research, can be conducted on laboratory animals.

The Cellvizio LAB is perfectly suited for the in vivo imaging trend in small animals that appeared at the end of the 1990s. To date, the Cellvizio LAB is still the only instrument capable of providing this type of information in vivo in situ in a minimally invasive way for oncology, neuroscience or stem cell researchers. Other microscopy instruments (called intravital microscopy or rigid endomicroscopy) cannot access internal organs without a considerable, and often terminal, procedure.

More than 150 articles in major scientific journals have been published by Cellvizio LAB users since 2005, attesting to its benefit for this booming market segment.

There are nearly 20,000 research laboratories around the world and numerous research centers associated with large pharmaceutical companies.

Mauna Kea Technologies has, however, done a strategic repositioning by focusing on the one hand on purely translational preclinical applications (i.e. with short- and medium-term scope in the clinical field) and at the same time by launching a specific program dedicated to clinical applications of optical molecular imaging clinics that are growing rapidly and are an integral part of the incredible emergence of Precision or Customized Medicine techniques.

Based on its unique approach, Mauna Kea Technologies brings to this new market excellent value propositions that are well identified and recognized by the majority of key players. The know-how from both preclinical molecular imaging and in vivo patient histology in a variety of therapeutic areas will make the Cellvizio technique an essential pillar of image-guided precision therapies; the latter can be for example extremely precise image-guided surgery, targeted deposits of therapeutic molecules, or measurements by endomicroscopic imaging of responses of a given patient to micro-doses of drugs to predict the efficacy of the treatments considered. All these applications have been tested in clinical trials including Cellvizio and will constitute important segments for development for Mauna Kea Technologies in the coming years.

### 6.4.4 Competition

**Optiscan/Pentax**

The Australian company Optiscan has developed a technical solution for endomicroscopy which is not based on the same technological choices as the Cellvizio, and has licensed their system to the Pentax group (since purchased by Hoya).

Owing to a lack of adequate performance (image cadence too slow, diameter too large and rigidity too great), the clinical and commercial development of this system has not met Optiscan's expectations; the company has not been able to finance it themselves and in fact suffered heavy losses (source: Optiscan Annual Report 2013). Today, Optiscan has no more agreement with Pentax (since July 2009), which has interrupted the marketing of the product derived from the Optiscan technology.

In small animal imaging, Optiscan markets a system called FIVE 1, which is a rigid endomicroscope 6 mm in diameter (Source: Optiscan). This system does not enable the non-invasive exploration of small animals, and also suffers from the same image rate limitations. In 2015 the company raised new funds ($0.5 million, Source: proactiveinvestors.com.au) to launch a small-animal imaging device in September, the CellLive, marketed by MR Solutions. No sales of this device have yet been reported.

[16] *http: //www.ncbi.nlm.nih.gov/pubmed/24091499*

[17] *http: //gi.org/guideline/diagnosis-and-management-of-neoplastic-pancreatic-cysts/ and http://www.cdc.gov/nchs/fastats/hospital.htm*

**Optiscan / Zeiss**

Relying on similar technology (same diameter and same frame rate) but this time in collaboration with the company Zeiss, the company Optiscan has developed a semi-rigid endomeicroscope dedicated to neurosurgery called ConVivo. In 2018 Zeiss obtained marketing authorization for this product from the US authorities.

**Olympus**

Olympus, the Japanese world leader in flexible endoscopes with 71% market share (Endoscopy Devices Market to 2016, GBI Research, December 2010), does not have any kind of commercial system for endomicroscopy. A prototype called "endocytoscope" has been shown in some conventions and conferences with very preliminary and mixed clinical results (source: American Gastroenterology Association http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/endocytoscopy.pdf. Citation: "the diagnostic performance of EC for the differentiation of Barrett's epithelia has been suboptimal. In a recent study, the application of EC in Barrett's esophagus resulted in a high proportion of unusable images because of suboptimal image quality, fair interobserver agreement, and poor diagnostic specificity").

This prototype, which appears to only be used in a single center in the world (in Japan) today, requires the use of several stains (ibid.) and does not appear to be adapted to any routine clinical practices. Moreover, the few rare publications about this experimental device note major difficulties for physicians in managing image interpretation to make it reproducible (ibid.).

**Fujifilm**

Fujifilm is one of the main actors in flexible endoscopy, under the Fujinon trademark. Fujifilm offers advanced imaging systems on its high-end flexible endoscopes under the name FICE (Fuji Intelligent Color Enhancement) and LASEREO which was launched at the end of 2015. This is a system of electronic filters or a laser source used to enhance some of the colors in the image. Developed to help tissue characterization, the FICE system was shown to be inferior to the Cellvizio in an independent study carried out by the Mayo Clinic (reference: Comparison of Probe-Based Confocal Laser Endomicroscopy With Virtual Chromoendoscopy for Classification of Colon Polyps, Buchner et al, Gastroenterology, January 2010).

Moreover, the Company set up a distribution partnership with Fujifilm at the end of 2012 for the Chinese market, which has just been renewed in 2016.

Although the Group and Fujifilm are present on the same market, the Fujifilm endoscopes are not in direct competition with the Cellvizio.

**SpectraScience**

The American company SpectraScience has developed a system for spectroscopic interrogation of colorectal polyps called Wavstat. This device does not produce images but rather analyzes the light backscattered by the tissues that make up the polyps and uses a proprietary algorithm to provide biochemical data. This device was distributed by Pentax in some regions, but this was stopped fairly rapidly. SpectraScience is listed on the stock market, however its value is currently less than $1 million and its share is quoted at $0.0005.

**Oncoscope**

The American company Oncoscope has developed a tissue interrogation system called SCOBE-E, designed to detect precancerous lesions in the esophagus. This system does not provide any images, but instead a mathematical analysis of tissues. It has only been tested clinically on 34 patients and has not yet been awarded FDA approval or CE marking for marketing (source: Oncoscope).

The company closed down in 2015 (Source: bizjournals.com) and its assets were taken over by SpectraScience.

**NinePoint Medical**

NinePoint Medical, a company based in Cambridge, Massachusetts, signed a licensing agreement in December 2010 for Massachusetts General Hospital patents concerning in vivo optical tomography technologies. The company obtained a 510k agreement from the FDA for its Nvision device which allows high-resolution imaging of part of the esophagus. This system is used in around 50 American hospitals. At the DDW 2017 conference, a meta-analysis of all Nvision studies of the esophagus showed that there was only a very marginal increase in the detection of dysplasia with a very high rate of false positives. The clinical benefits of Nvision have thus not yet been demonstrated, even if the procedures may theoretically be reimbursed with the same CPT codes as Cellvizio® (source: NvisionVLE® Imaging System - NinePoint Medical website).

**LLTech**

The French company LLTech markets microscopic tomography technologies developed by researchers at ESPCI (industrial chemistry and physics college). Today, the company is focusing on the research and histopathology markets (Source: LLTech). It also communicates regularly on upstream technical developments relating to rigid endomicroscopy.

**Caliber ID (formerly Lucid Inc.)**

The American company Caliber ID has developed a system of in vivo microscopy for exclusive use in dermatology. No endoscopic application appears to be planned at this time.

### 6.4.5 The platform's growth relays, as a Group and via partnerships

Although the Group began selling in the gastroenterology, then pulmonology sectors, in 2013, it also obtained marketing agreements for a range of miniprobes dedicated to urological applications, then for laparoscopy in 2015. Indeed, Mauna Kea Technologies intends to extend its commercial offer to other endoscopic and surgical fields. Microscopic vision is key for many cancers as well as many other diseases, and the Cellvizio could provide a minimally invasive instant response to many diagnostic problems.

**Interventional pulmonology Market**

Lung cancer is still the leading cancer in men, although its incidence has stabilized (*source: American Cancer Society 2008 - stats)*. The incidence in women continues to increase slightly. Lung cancer is the most common cause of death in the western world for both women and men. The prognosis for lung cancer depends on several factors, one of the most important being the stage of development when the cancer is diagnosed. Patients who present with peripheral lesions less than three centimeters in diameter (T1) are the best candidates for surgical resection and have the best chance of survival, with a five-year survival rate of 60% to 80%. Fewer than 1% of patients suffering from an advanced stage of cancer are still alive five years after diagnosis. (*Source: World Health Organization*).

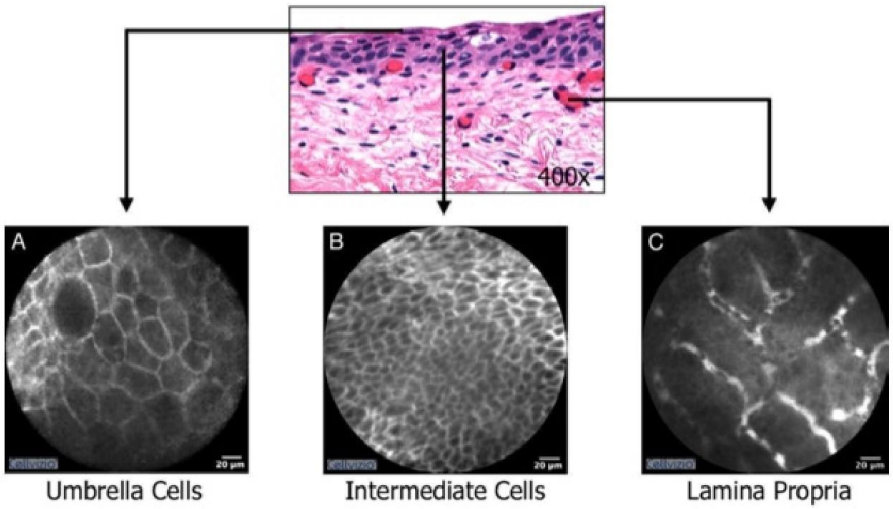
Once the patient exhibits symptoms, the disease is generally quite advanced at the time it is diagnosed and the vital prognosis is quite critical. Most often, however, a peripheral nodule (a small mass, either benign or malignant) is found in the lungs during a routine exam, like a CT scan. The problem is characterizing such a nodule in order to direct therapy in the most appropriate way. With the improvement in wide field imaging techniques such as scans, and the introduction of lung cancer screening programs, the number of nodules identified during these imaging examinations is multiplied, as is the need for characterization. American scientific societies have recently recommended screening for these pulmonary nodules, because it has been shown that screening improves the prognosis for patients while reducing the cost of treatment (source: Powell et *al., Ann Surg. September 2004; 240(3): 481–489, et CHEST / 142 / 2 /385-393 AUGUST 2012).*

Several techniques can be used to characterize a pulmonary mass. The most effective, when possible, consists in physically sampling a piece of tissue from the nodule, either via a biopsy through a bronchoscope, sometimes equipped with an electromagnetic navigation device in the pulmonary tract, or by taking a transpleural biopsy with external access. In the first case, the procedure is low risk but the current diagnostic performance of these procedures is low due to sampling errors. In the second case (trans-thoracic access), the procedure is complex for the patient, since it is very invasive, and in the end it is not used much. With the advent of new robotic navigation systems, Cellvizio could make it possible to guide this procedure by inserting the AQ-Flex probe in a transbronchial needle to take biopsies with good diagnostic information, thus improving the efficacy of the procedure and giving the patient faster access to treatment if needed. The recent studies published by the group of Pr. Annema in Amsterdam are in line with this very strong value proposition.

*An AlveoFlex confocal miniprobe being inserted into a bronchoscope.*

The bronchoscopy market is very similar to the digestive endoscopy market as far as medical equipment is concerned: all healthcare facilities that have an endoscopy unit with at least one bronchoscopy room that could be outfitted with the Cellvizio. This represents more than 60,000 hospitals and clinics in Europe, the United States and Asia. The number of bronchoscopy procedures is estimated at about 500,000 exams per year in the United States with more than 240,000 biopsies taken per year. These figures are constantly increasing. This volume, although less than that of digestive endoscopy, is reflected in a potential of several hundred thousand Cellvizio procedures in the pulmonology field, and the associated renewal of several tens of thousands of Confocal Miniprobes per year. *Source: Center for Disease Control and Prevention, ww.cdc.gov*

**Endo-Urology Market**




*Example of Cellvizio images obtained in the bladder and correlated to the standard histology.*

Endo-urology is an area of urology that consists of examining the urinary tract endoscopically to look for obstructions or cancers, and when necessary performing endoscopic treatment procedures. The most common exploration performed in endo-urology is cystoscopy, an examination of the bladder. There were approximately 71,000 new cases of bladder cancer in the U.S. in 2010, and 15,000 deaths from this disease. One in 27 men will develop this disease in his life, as will one in 85 women. Nearly 90% of patients with this cancer are over the age of 55.

(*source : American Cancer Society, https://www.cancer.org/*).

The management of bladder cancer requires several cystoscopy procedures.
The first one is usually performed in the physician's office with a flexible cystoscope to find evidence of a lesion.
The second procedure, performed in the operating room with a rigid cystoscope, is to obtain biopsies of the lesion.
When possible, the third will be to perform an endoscopic resection of the tumor, although this is not always possible as too many cancers are diagnosed at an advanced stage.

One-quarter of patients present with a cancer that has invaded the muscle and/or metastatic barrier, while over 20% of patients have a cancer that is less advanced but already high grade. The bladder cancer recurrence rate is quite high, between 50% and 90%, which requires continual life-long surveillance for patients who survive this disease. This surveillance is conducted via repeated cystoscopy procedures at regular intervals. These multiple diagnostic and follow-up endoscopic procedures make the management of bladder cancer the most costly of all cancers, representing approximately $3.7 billion in the U.S. in 2001 (source : Jemal A, et al. CA Cancer J Clin, 2010. 60(5):277-300.)

The cystoscopy market is estimated as follows:

- in *France, (Source: ATIH*, 2008), the number of diagnostic cystoscopy procedures is estimated to be 37,000 per year, and the number of therapeutic cystoscopy procedures is estimated to be 52,000 per year. On this basis we can estimate that there are approximately 470,000 diagnostic cystoscopy and 670,000 therapeutic cystoscopy procedures in Europe every year;
- in the United States *(source: NHSR, Number 11, 2009, "Number of ambulatory* surgery procedures, US, 2006"), there are 750,000 diagnostic cystoscopy procedures and around one million therapeutic cystoscopy procedures each year.

As for bronchoscopy, all healthcare facilities that have an endoscopy unit have at least one cystoscopy room that could be outfitted with the Cellvizio.

Cellvizio may be used during diagnostic and therapeutic cystoscopy procedures, as shown in several studies by Pr. Liao of the VA Hospital of Palo Alto *(source : Interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi : 10.1089/end.2012.*0549, May 2012). Clinical work is in progress to confirm this American data with European results. Using the Cellvizio in endo-urology seems to provide a critical benefit in optimizing the transurethral resection procedure for precancerous and cancerous lesions, in identifying further lesions not identified during the primary diagnostic examination (flexible cystoscopy), as well as post-resection follow-up, which could eventually lead to a reduction in recurrences.

The volume of procedures represented by endo-urological applications is significant. Finally urology is a specialty at the frontier between endoscopy and surgery, so urological indications may provide Mauna Kea Technologies with an entry onto the surgical applications market, which is a major challenge for the company.

In December 2015 Mauna Kea Technologies signed a commercial partnership agreement with Cook Medical concerning urological indications. The agreement required Mauna Kea Technologies to develop a customized version of the Cellvizio in 2016, reflecting the corporate identity of Cook Medical. Thanks to its international commercial expertise, its marketing and medical know-how and its comprehensive portfolio of complementary products for urological applications, Cook Medical could quickly optimize sales opportunities for Cellvizio. The Cellvizio Cook prototypes were successfully unveiled at the Annual EAU Congress, the AUA Annual Meeting and the World Congress of Endo-urology (WCE) in 2016.

**The surgical market**

Very open to innovation and naturally including endoscopy-related devices as part of the treatment for certain types of cancer (digestive, pulmonary and urological), surgeons are naturally interested in the Cellvizio, seeing it as a tool which can help them refine their procedures, for better preservation of function in resected organs, while ensuring complete eradication of cancerous cells.

In 2010, Mauna Kea Technologies and its PERSEE project partners (a collaborative project supported by the OSEO/ICI program; see Section 6.6.1.2) began developing a robotic-assisted, minimally- invasive endomicroscopic exploration solution for the abdominal cavity to improve the management of cancer patients, with the goal of reducing the number of unneeded and/or incomplete surgeries (up to 25% of pancreatectomies, for example). The prototype was tested during a feasibility clinical trial on patients, which took place in 2015. In 2016, during the American SAGES conference, two posters were presented and given a very favorable reception. The PERSEE project is structured into four successive phases, the last of which is due to be completed in May 2016. In practice, the third of these phases was finished in July 2015, and the stage 3 end report was submitted to BPI France in May 2016. In 2018, the fourth phase was initiated; In 2019, the Company obtained the agreement of BPI France to extend the term of Phase 4 until October 31, 2020, the end of the project.

Moreover, Mauna Kea Technologies is devoting ever more time and effort to developing endomicroscopy systems for surgical specialties, through:

- identification of this development as a central company project;
- the recruitment of dedicated resources;
- the integration of operating theater restrictions in designing its next generation Cellvizio systems;
- launching clinical trials specifically concerning surgical applications, whether at the Group's initiative or directly by surgeons who have used the Cellvizio.

These clinical trials are currently in progress or planned in the fields of laparoscopic abdominal surgery, neurosurgery, robotized surgery for urological and gynecological cancers, and colorectal surgery.

## 6.5 Marketing and partnerships

### 6.5.1 Marketing strategy: refocusing on indirect sales

Since the beginning of 2017, the Company has dedicated a significant portion of its commercial resources to the development of the gastroenterology market in the United States, which it addresses today with a dedicated sales team.

The other target market today is China, for which the Company has a regional distribution partner, Youhe Medical, and dedicated resources.

**The economic model**

The Company's business model is currently based, outside the United States, on the sale of equipment (or systems), consumables (called miniprobes) which can be used a limited number of times, and services. Specifically in the United States, the Group offers Cellvizio in the form of a supply program with billing on procedure only ("pay-per-use" program).

The latest generation of Cellvizio currently sold in most countries, to hospitals and clinics, is the Cellvizio *100*®. The Group has developed a range of miniprobes suitable for the Cellvizio 100. There is a miniprobe for each of the medical indications for which Cellvizio is marketed.

| (in € thousands) – IFRS | Q4 2019 | Q4 2018 | Change % | 2019 | 2018 | Change % |
|---|---|---|---|---|---|---|
| Systems | 390 | 874 | (55%) | 2,301 | 2,683 | (14%) |
| Consumables | 1,025 | 795 | 29% | 4,122 | 2,813 | 47% |
| of which "pay-per-use" program | 398 | 327 | 22% | 1,682 | 890 | 89% |
| Services | 275 | 450 | (39%) | 1,007 | 1,265 | (20%) |
| Total Sales | 1,691 | 2,120 | (20%) | 7,431 | 6,760 | 10% |

In 2019, revenue through sales of equipment represented 31% of the total sales, with consumables representing 55.5% and services 13.5%. In the medium-term, the percentage of sales of consumables is likely to progress as the installed base increases.

| Units (#) | Q4 2019 | Q4 2018 | Change % | 2019 | 2018 | Change % |
|---|---|---|---|---|---|---|
| New systems sold | 4 | 9 | (56%) | 25 | 26 | (4%) |
| Systems on consignment | 5 | 19 | (74%) | 17 | 55 | (69%) |
| Probes delivered | 178 | 170 | 5% | 800 | 663 | 21% |

In units, the Group sold 25 systems in 2019 against 26 in 2018, and delivered 800 probes in 2019 against 663 in 2018.

The overall gross margin on the units and probes remained stable at 70%.

On the date of this Universal Registration Document, the Group had an installed base of 673 units, mainly resulting from equipment sales and, to a far lesser extent, the provision of equipment.

Annual maintenance contracts or warranty extensions, software upgrades and offers of training are also proposed, generating a recurrent share in earnings which should gradually increase as the installed base increases.

**Dual commercial organization**

For sales to hospitals and clinics, the Group has applied a dual commercial strategy, with the deployment of a direct sales force in the United States, in France and in Germany, linked to a distribution network for all other countries in which it has obtained marketing authorization.

**A direct approach in the United States, in Germany and in France**

In these three countries, where the direct approach has priority, the Group has a sales force of two teams with different skills and responsibilities. The first team comprises equipment sales representatives (Area Sales Manager – ASM), while the second team is responsible for consumables sales and clinical support (Clinical Account Manager – CAM), mainly Cellvizio adoption and procedures, training for hospital personnel, and correct use of the equipment and probes during procedures. This second, so-called "CAM" team will provide support for our partner Cook Inc.

Each sale of equipment includes clinical training in how to use the Cellvizio, notably interpretation of the images obtained. The training covers all stages of use from plugging the equipment in to disinfecting the probe after the procedure.

The hospital medical teams responsible for the procedures receive long-term support to ensure that the Cellvizio is used under the best conditions. For this reason, during the first months of use, CAMs regularly meet hospital management for planning intervention, to work together to identify the patients whose pathologies are particularly suitable for the Cellvizio. The CAMs are also present in the endoscopy rooms during the procedure, to train the medical teams.

This commercial presence in the field is the determining factor in encouraging professionals to endorse this new tool, so that they include it in their clinical routine.

**An exclusive distributor network for the other countries**

The Group's sales strategy (excluding France, Germany and the United States) is based on a distribution network, used to ensure a presence in many areas. The Group has chosen in particular to be very active in the main countries of the European Union and Asia – especially China. The distributors have been selected according to the following criteria:

- comprehensive knowledge and mastery of the sector and specialty within their mission;
- "product" synergy leading to the Cellvizio being inserted into a complementary ecosystem;
- a proven ability to get across sometimes complex sales pitches quickly; and
- an ability to maintain a field presence, indispensable to promoting technology effectively.

This network includes nearly 40 distributors, who have exclusivity in their commercial area. The business of these distributors varies according to the areas and years. The distribution network is under the responsibility of the Director of Global Sales.

This person is tasked with operational support for local sales forces deployed by distributors, helping them with training and setting both strategic and operational objectives. He is in permanent communication with the distribution network and ensures that objectives are met. In China, the Group has set up local support for distributors.

To date, the Group is present mainly in the following geographic zones:

- Europe (United Kingdom, Germany, Spain, Italy, Belgium, the Netherlands, Scandinavia, etc.);
- Asia (Japan, China, India, Malaysia, Singapore, Thailand, etc.);
- Latin America.

As well as providing support for distributors, the Global Sales Director provides good "visibility" for the Group and its products in each zone:

- participating in professional conventions and "industrial" and "commercial" shows;
- organizing workshops intended to train prospects and clients;
- implementing in situ demonstrations at "target" medical centers;
- training distributors regularly on the technical aspects of the product as well as on the continually evolving purely clinical aspect of the system's applications;
- defining and approving communications that must be both coherent and homogenous, but also adapted to the cultural specificities and commercial expectations of the various markets.

The current list of the Group's commercial partners is available on the website at: www.maunakeatech.com.

**A specific indirect approach for the research laboratory market**

The market for small animal imaging systems dedicated to research having reached a new stage of maturity, in 2011 Mauna Kea Technologies decided to reorient its strategy and modify its distribution channels. Therefore, a new distribution network has been developed for a certain number of countries and direct commercial action instigated in others. This new approach has led to significant results and better anticipation of future needs on this market.

### 6.5.2 The brakes in sales development

The Group's sales plan has generally been slower than was envisaged at the time of its IPO in July 2011.

The brakes slowing down fast sales development are described in this paragraph.

*1) Lack of reimbursement in certain regions*

Lack of reimbursement is an obstacle to quicker distribution of Cellvizio (see Section 6.1 "6.1summary").

*2) The reorganization of the sales team in the United States*

In early 2016, the sales force in the USA was reorganized into two Eastern and Western divisions. At the end of 2017 and in early 2018, new sales representatives were recruited to develop the business in the United States. This sales force is under the direct responsibility of two Regional Sales Managers and a Vice President of Sales who reports directly to the Chief Executive Officer.

*3) The impact of Obama Care (Accountable Care Act and Affordable Care Act)*

Passed in 2011 but actually coming into force in 2014, the in-depth reform of the American health system orchestrated by Obama Care had a double negative consequence for the medical equipment market in the United States.

On the one hand, healthcare establishments have been forced to invest massively in Computer Management Systems (IT) to modernize their information systems and this has meant using part of their investment budget for medical equipment on their IT infrastructure instead.

On the other hand, this led to serious disturbances in their medical equipment purchase practices and their methods of evaluating this equipment. The introduction of new practices, new decision circuits and new models for Return on Investment led to a prolongation in sale cycles.

*4) Adoption curve: gastroenterology departments are slow to adopt new technologies.*

Finally, and this may be the biggest brake of all, gastroenterologists, who normally form our leading market segment in the hospital market, have been slower to accept the Cellvizio than the Company had envisaged. The increase in the CMS reimbursement rates these last few years and again in 2019 will help change this situation.

*5) Ecosystem: A technology which needs to be integrated*

The complementarity of equipment constituting an operating room is an essential key to sales in the hospital market. The Company must search for industrial partners in order to incorporate its endomicroscopic technology in a complementary and coherent ecosystem.

*6) Service offer: An economic reality*

The economic pressures on health centers are forcing them to reduce their capital investments and promote the use of leased or pay as you go equipment. The Group has developed such offers with the intention of providing access to the Cellvizio through a service offer, a finance lease offer and a pay-per-use offer.

### 6.5.3 Partnership and business development strategies

The Company has been pursuing business development initiatives to expand its market reach, build brand awareness, and broaden its clinical and technological capabilities through various types of research and commercially oriented partnerships.

**Existing partnerships**

In 2017, the Company entered into a distribution agreement with Youhe Shanghai Medical Technology Co. Ltd, with the aim of reviving sales of Cellvizio in China.

The Company will continue to seek research and commercially oriented partnerships with select companies with technical expertise or strong brand presence in specific markets that are of strategic interest to the Company. Such partnerships could allow the Company to grow at a faster rate and potentially be more profitable than it otherwise could achieve on its own. Examples of areas of interest include: endoluminal (GI and lung applications), surgical, interventional radiology and biopharma applications.

## 6.6 Transactions

### 6.6.1 Internalization of the high value-added stages

The Company externalizes part of its production line, only retaining the high added-value stages which include the Company's core expertise.

In this context, as well as identifying and selecting raw material suppliers (lasers, mobile mirrors, mechanical control components, electronic components, etc.), the Company has developed a network of subcontractors to fulfill certain stages in the manufacture of the laser scanning unit (pre-assembly of mechanical components for the unit's optical base, incorporation and wiring of electronic cards and power supplies). As for the production of miniprobes, the Company decided to subcontract the manufacture of certain models of miniprobes or part of their assembly so as to optimize its capacity and production costs, while retaining internal control and expertise for high added-value operations.

Because of the quality of the design which was defined and validated during the product design stage, whether specially made parts (e.g. optical lenses) or shelf parts, manufacturing procedures are optimized. The result is a cost price largely composed of material costs.

### 6.6.2 Lean “Manufacturing”

As part of its quality assurance and continual improvement effort, the Company has also been working since 2008 on Lean Manufacturing projects, bringing together the R&D, quality, production and supply chain teams.

Lean Manufacturing is a production management system based on three fundamental elements:

- cost reduction by eliminating waste;
- just-in-time production;
- quality.

Having these three elements function interdependently and optimally provides sustainable and efficient results, and enables the enterprise to be more competitive and to adapt to any market development.

This production organization enables the Group to maintain a high level of reactivity in view of the uncertainty concerning the speed of deployment of the equipment in order to meet customer requirements as quickly as possible.

The implementation of a “lean” procedure has also helped to more than double production capacity since 2008, with constant resources and to reduce the cycle time by a factor of three.

In 2010, the Company also decided to subcontract the optomechanical assembly of a first model of Confocal miniprobes from a supplier who is an expert in optical fiber and precision optical assembly. Complete validation of this subcontracting was finalized early in 2013 so that the Group can now pass part of its miniprobe production to this partner, thus ensuring a growth in productivity without further investment. This approach has been extended since 2014 to other miniprobe assembly stages and since the end of 2016, the Company transferred the assembly of one of these Miniprobe models to this same subcontractor. Finally, in 2019, the Company extended this subcontracting process to the new range of Miniprobes, whose design has been revised to enable compatibility with the next version of its Cellvizio system planned to be marketed in 2020.

After all the work done in Lean Manufacturing to improve productivity, and considering the structure of the current production team and the subcontracts carried out, the Company can now guarantee production of Cellvizio systems and miniprobes and, through outsourcing, expect to enlarge its capacity for the next two years, in accordance with its business plan and without significant investment.

The Company must change its internal processes to implement a growing range of products efficiently, based on identical technological bricks, adapted to different product or market requirements. In 2016, the Company therefore moved its production premises to the ground floor of the building it was occupying at the time, together with its other operational departments (purchasing, logistics, customer service, quality). As well as gaining extra square meters, the newly developed production premises will provide

space to grow as the number and models of products manufactured increases, and to facilitate logistics flow to and from the production areas, as well as product inspection and testing.

#### 6.6.3 Quality Assurance

The Company has included quality in its management system since its creation in 2000 and the first ISO 9001 certification was obtained in 2002. It was extended to ISO 13485 for medical devices in 2005.

The Company updated its quality management system to comply with the new versions of quality management system standards (ISO 9001: 2015 and ISO 13485: 2016 for medical systems), and achieved certification on these new versions at its renewal audit at the end of 2017.

It also provides a continuous monitoring process on the standards and regulations which are applicable to its products to guarantee that they remain in compliance in the various countries where they are marketed. For example, the Company has introduced a unique identification system ("Unique Device Identifier" – UDI) for its medical products to meet new requirements which came into effect in the United States in September 2016.

This system was extended in 2018 to mark reusable consumables (confocal miniprobes) directly with a UDI in accordance with FDA requirements. This work also anticipates compliance with the unique identification requirements of the European Regulation DM 2017/745.

The production line is thus certified during certification renewal audits (every three years) or annual monitoring, certification covering activities linked to procurement, product manufacture and packaging.

In this context, all major changes to the production line (subcontracting, offshoring, etc.) must be reported to the third-party organization and may be audited to ensure that certification is maintained.

Quality controls are carried out on raw materials entering the production line, during the different stages of manufacturing and on the finished product before shipment.

Finally, in 2019, the Company committed to a process to obtain its certification as an Authorized Economic Operator in accordance with the provisions of Article 22 of European Regulation 962/2013 establishing the European Union's Customs Code. The audit was completed in December 2019 and was conducted without any non-compliance. The Company believes it will obtain its certification at the beginning of 2020.

#### 6.6.4 Selection and monitoring of suppliers and subcontractors

The Company identifies and selects suppliers with the industrial capacity necessary to support its commercial ambitions. The choice of partners meets product and regulatory constraints, production capacity meeting the Group's ambitions, and economic and profitability considerations.

Raw materials are the biggest part of production cost, the purchasing process being a key company process, split into several areas:

- Partners related to the production chain are selected jointly by the Research and Development division and the Purchasing department. Once the selection has been made, the R&D department works upstream with subcontractors to produce the first prototypes, and with suppliers to validate critical or sensitive components and assemblies (i.e. meeting critical technical specifications or having strong impact on product quality and safety). Once the partner has been validated, the service is contractualized by the Purchasing department on the basis of the specifications validated during production engineering. Critical suppliers and subcontractors must therefore report any changes to their own production line (raw materials, manufacturing methods and processes, offshoring or subcontracting, etc.) and submit them to the Company for approval.
- Suppliers and subcontractors are monitored and evaluated by the Purchasing department, based on multiple criteria covering, for example, respect of deadlines, delivery non- compliance, organization, financial declarations, etc.
- The Company regularly audits sensitive suppliers based on an annual schedule drawn up by the Purchasing and Quality Assurance teams and according to evaluation results. In 2019, six supplier audits were carried out.

#### 6.6.5 Selection of main partner subcontractors

Of the Company's current industrial partners, the optical fiber supplier Fujikura is particularly important in so far as the Cellvizio has been completely designed (imaging system, image processing) on the basis of this component. Based in Japan, this company, a leading global player in the manufacture of optical fibers, has entered into a long-term partnership with the Company and became a shareholder in 2006.

The Company implemented an externalization strategy with Fujikura by transferring some of the assembly stages of certain Confocal miniprobe models to benefit from this supplier's industrial expertise.

The company's other subcontractors carry out specific assembly steps (mechanical or electronic integration of components on specifications) or translation work, allowing the company to concentrate its workforce on the stages of production with high added value.

In 2015, the Company also approved a new subcontractor for the production of electronic boards and electromechanical incorporation of its laser housings for the medical field. This work has led to a joint project between the R&D, purchasing, production, regulatory affairs and quality teams, and provides a simplification of supply chain logistics and reduced manufacturing costs.

In 2018, the Company hired a new subcontractor for the manufacture and the cabling of the mechanical trolley integrating the components of the Cellvizio 100 Series.

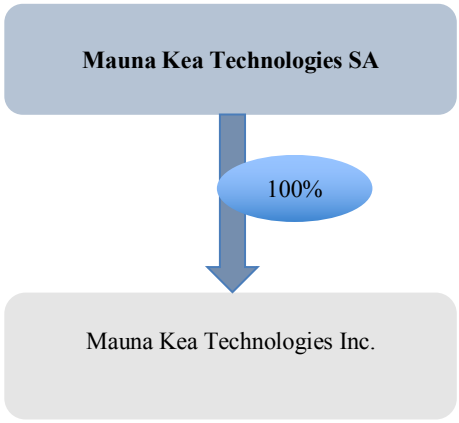
Lastly, as part of the development of Cellvizio's new model (Cellvizio I.V.E.), the Company has renewed a large portion of its supplier panel, all of whom qualified in 2019. This work enabled it to guarantee a diversity of supplier sources, in particular in the fields of precision mechanics and electronics.

Finally, regarding the logistics department, the Company uses different service providers depending on local constraints (country, delivery times, need for local storage, etc.). The selection of logistics subcontractors offering local finished products storage (for example in the United States) ensures a delivery time to end customers comparable to market standards and adapted to their needs, particularly in the case of Confocal Miniprobes.

# SECTION 7
# 7. ORGANIZATIONAL CHART

## 7.1 Legal entity organizational chart

As of the registration date of this Universal Registration Document, the legal entity organizational chart of the Mauna Kea Technologies Group is as follows:




## 7.2 Group companies

**Mauna Kea Technologies SA**: Based in Paris, Mauna Kea Technologies SA is the Group's parent company.

**Mauna Kea Technologies, Inc.**: Based in Boston, Massachusetts, Mauna Kea Technologies, Inc. was founded in 2005. This entity markets the Group's products on U.S. territory and provides an interface with the regulatory authorities (FDA). At December 31, 2019, it had 25 employees and posted sales of $3,824 thousand (or €3,416 thousand, at a conversion rate of 1.1196) and a net loss of $5,935 thousand (or -€5,301 thousand, at a conversion rate of 1.1196).

## 7.3 Principal intra-group flows

There are primarily three kinds of intra-group flows.

**a) Commercial flows**: Since all equipment sold everywhere in the world is made in France, the Company signed an exclusive distribution agreement with its American subsidiary giving the latter exclusive territory rights to distribute the Group's products (equipment and consumables) in the United States and Canada.

**b) Reinvoiced services**: A services agreement was signed on January 1, 2010 between the Company and its American subsidiary for an initial term of five years, renewable annually. Therein it is provided that the Company contributes its assistance to Mauna Kea Technologies, Inc. in five areas:

- ✓ Management of the subsidiary;
- ✓ Accounting and financial assistance (drawing up budgets and their follow-up, implementing control tools, advising on relations with banks, tax assistance, etc.);
- ✓ Commercial assistance (defining strategic plans, marketing plans, organizing commercial events, sales administration, assistance in terms of product regulation management, etc.);
- ✓ Technical assistance (sales support, maintenance and improvement in quality control);
- ✓ Assistance in terms of human resource management (recruiting key associates, training, employment regulations, dedicated IT tools, HR policy, etc.).

The agreement provides that the inherent costs of the assistance services actually provided will be invoiced by the Company to its subsidiary at real cost, plus a 3% margin. The cost of services that the subsidiary could, as the case may be, have provided to the Company in these same areas will be deducted from the amounts owed.

For the 2019 financial year, the Company invoiced its subsidiary for the amount of €674 thousand.

**c) Financial flows**: A Group cash management agreement was signed on October 11, 2005. Advances made by either of the two entities of the Group are remunerated on the basis of the legal interest rate in France.

For the 2019 financial year, the Company invoiced its subsidiary for interest totaling €438 thousand.

# SECTION 8
# 8. PROPERTY, PLANT AND EQUIPMENT

## 8.1 Property and equipment

### 8.1.1 Leased property

The following are the only premises used by the Group:

**Head office in Paris**: Located at 9 rue d'Enghien, Paris (75010), the Company's registered office covers five stories of the building with a total floor space of about 1,133 m² (basement included). The Company became the lessee of the premises as and when it expanded and has five separate leases contracted with SCI Enghien 9, which is the owner thereof and which has no capital link with any of the managers and/or shareholders of the Company. The various commercial leases entered into by the Company within the property are summarized as follows:

| Location | Surface Area | Start Date | Term | Expiry of the lease | Initial lease payment in € excl. VAT per year |
|---|---|---|---|---|---|
| Ground floor | 365 $m^2$ | Mar. 1, 2016 | 9 years | Feb. 28, 2025 | 98,666 |
| 1st floor right-hand side | 115 $m^2$ | Jun. 1, 2005 | 9 years | N/A | 21,915 |
| 1st floor left-hand side + underground parking | 223 $m^2$ | Oct. 1, 2000 | 9 years | N/A | 42,495 |
| 2nd floor (right-hand side) | 115 $m^2$ | Jan. 1, 2005 | 9 years | N/A | 21,915 |
| 2nd floor (left-hand side) + underground parking | 223 $m^2$ | Feb. 1, 2004 | 9 years | N/A | 42,495 |
| 3rd floor + basement | 157 $m^2$ + 60 $m^2$ in the basement | Nov. 1, 2008 | 9 years | N/A | 40,820 |
| 4th floor | 140 $m^2$ | Nov. 1, 2009 | 9 years | N/A | 32,240 |
| 5th floor | 100 $m^2$ + 20 $m^2$ of terrace | Nov. 15, 2013 | 9 years | Nov. 15, 2022 | 30,000 |

By applying the price adjustment conditions provided for in the leases, the Company recorded a rental expense (excluding rental charges) of €406 thousand for the year ended December 31, 2019.

**Sub-leasing**: at December 31, 2019, the Company continued to sub-lease its fourth floor and the right side of its second floor under conditions identical to those of the main lease.

**Offices in the United States**: Initially based at 185 Alewife Brook Parkway in Cambridge, Massachusetts, until February 2017, the subsidiary moved its offices to 24 Denby Road in Allston, Massachusetts. The rental charges recognized in the United States for the 2019 financial year total $67 thousand.

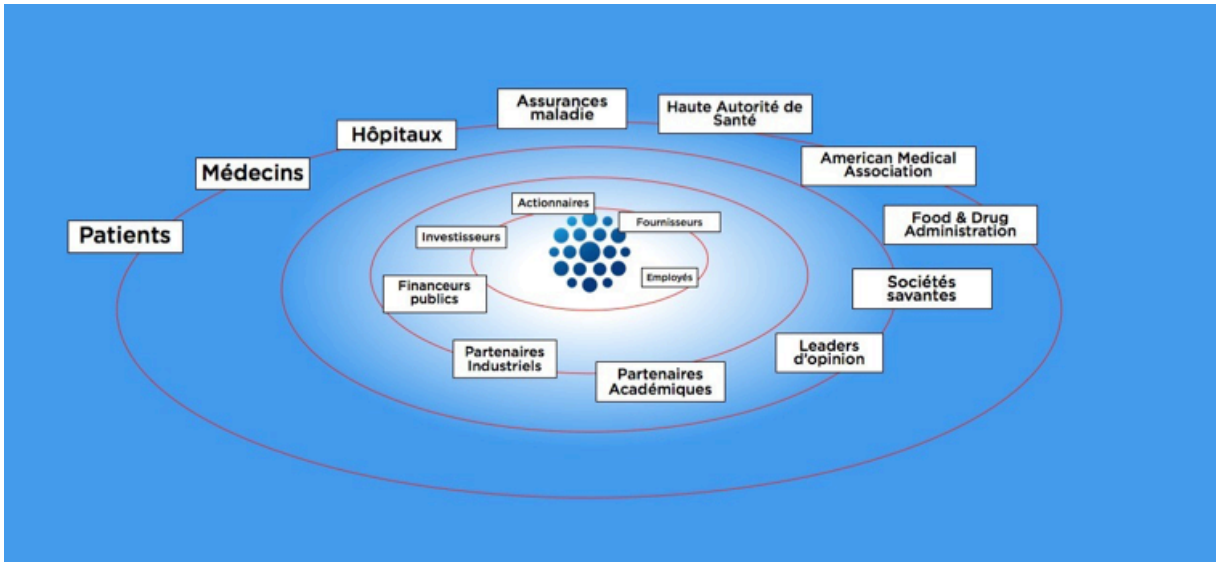
### 8.1.2 Other tangible assets

The principal property, plant and equipment held by the Company are described in Note 4 to the 2019 consolidated financial statements, appearing in 20.120.1 of this Universal Registration Document.

## 8.2 Resources and Synergy

**Relationships with stakeholders**

Mauna Kea Technologies is evolving at the heart of a complex ecosystem that includes many players:




The end users of its products are the patients; Doctors, healthcare facilities and research centers are the customers. 673 sites currently have the Cellvizio® technology. The Company has thus developed strong relationships with the medical community, and in particular with opinion leaders, who have experience with our medical devices, and the scientific authority necessary for the adoption of a new medical technology by their colleagues.

Scholarly societies and professional medical associations have an important influence in obtaining reimbursement codes, or in implementing sound medical practices based on national or international recommendations.

Healthcare authorities and health insurance organizations issue marketing approvals and reimbursement codes.

Academic partners with which Mauna Kea Technologies conducts research work.

Industrial partners, whether customers or suppliers, with which Mauna Kea Technologies has built up strong, lasting partnerships.

Outside of the medical field, the Company maintains close relationships with both the European and the U.S. financial community. It has a shareholder base of several thousand individual French shareholders, which is the vast majority, and individual European and U.S. institutional investors, general fund managers or healthcare specialists.

Lastly, the Company's employees share, maintain, and develop the values of Mauna Kea Technologies.

## 8.3 Societal impact

### 8.3.1 Medical environment

Patients are at the heart of its business activity and its aim is to give users the means to eliminate diagnostic and treatment uncertainties when tracking tissue, cellular and even molecular organization.

With this approach, Mauna Kea Technologies is developing a range of medical and clinical evidence using various resources, including an exhaustive review of the scientific literature on the technology and its clinical applications.

**Carrying out clinical investigations**

These are aimed at providing sufficient proof to demonstrate the safety, efficiency, and benefits of medical devices for the health economy. Mauna Kea Technologies is the sponsor of several clinical trials in line with the international standard ISO 14155. A rigorous process is followed: for each trial, a clinical study plan (protocol) is submitted to the ethics committees and the competent national authorities upon which the participating study centers depend, and according to their local legislation.

The protocol describes in detail the nature of the trials carried out, and is committed to demonstrating the pertinence of the study, by giving priority to the potential benefit for the patient and the associated risks.

The patients who participate in the trial receive an information notice, which specifies the nature of the trial in which the physician proposes to include them, the risks involved, and the benefits of the clinical evidence, which may be concluded from this trial.

They thus co-sign an "informed" consent with their investigator-physician, and keep a copy.

Only the data that is pertinent to the clinical demonstration is gathered during the clinical trials. All personal and/or sensitive patient data is processed in compliance with the laws and regulations in force pertaining to data protection, management, and processing. Identifying information is removed from all data gathered for a specific patient, and is sometimes coded, in order to guarantee respect of their privacy.


Mauna Kea Technologies makes regular visits to the study sites in order to ensure compliance with the protocol, and each year sends an analysis to the ethics committees, pursuant to local legislation and requirements.

All investigators and/or their institutions draw up a specific agreement for each trial with the Company, in order to reiterate their independence, the respective duties of the parties, and the terms of compensation, in compliance with local legislation and the principle of transparency. They thus maintain their full freedom of expression regarding the technology and its performances.

Mauna Kea Technologies has also identified experts in different specialties to support it in decision-making and validation of clinical evaluations of its products: the Medical Advisory Board comprised of expert doctors - opinion leaders - which helps to define the Company's clinical development strategy.

**Monitoring the use of medical devices after they are placed on the market**

In order to manage such activities, Mauna Kea Technologies remains attentive to its clients and to their feedback on the use of its products, by providing input to the continuous process of improvement.

As part of its monitoring of activities connected to the Quality Management System (QMS), internal audits are regularly performed, in order to check the conformity and effectiveness of the key activities of the Company, such as clinical affairs, Post-Market Surveillance (PMS) or materials vigilance. These audits are performed by auditors who are independent from the activity being audited.

Within the context of product use in a medical environment, a specific process of Post-Market Surveillance and of materials vigilance has been put into place. This makes it possible to gather data on incidents presenting a potential risk to patient or user health connected to the use of our products. The incidents are analyzed, in liaison with the physician-users, in order to decide whether the incident should be reported to the national health authorities. This process was reviewed in 2019 to comply with the new European Regulation on Medical Devices. In 2019, the Company reported 4 incidents, all of which occurred in the Persée clinical trial. None of these potential adverse events had patient health consequences, and three were post-operative complications unrelated to the use of the Cellvizio system. The overall rate of incidents related to the use of the Cellvizio system remains low and lower than the published incident rate for endoscopic or surgical procedures in which the system is used. It also remains stable despite the constant increase in the number of Cellvizio procedures.

**Maintaining information for healthcare professionals**

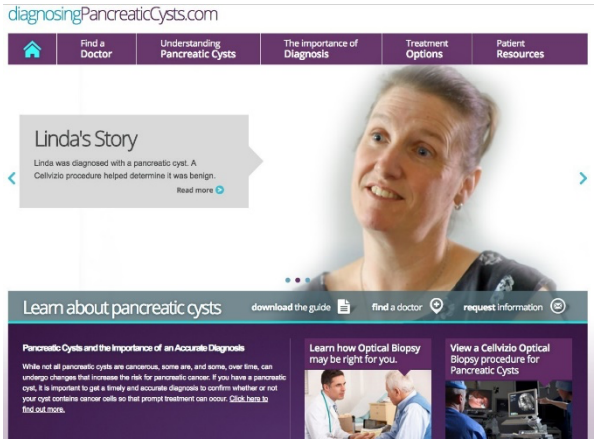
In 2017, the Company completely revamped its e-learning site, cellvizio.net, aimed at healthcare professionals to make it easier to use and enriched with the latest information.

Mauna Kea Technologies regularly sends out newsletters and also encourages its users to undertake continuous training in the form of workshops and support for symposia, on-site training when equipment is installed, supporting users in their initial procedures and providing tutoring by expert users. A new smartphone application called Cellvizio was developed in 2017 and enables product images to be viewed.

**Providing information to patients**

In 2013, Mauna Kea Technologies launched two websites dedicated to the following indications:


| | |
|---|---|
| Pancreatic Cysts | Barrett's esophagus |
| http://diagnosingpancreaticcysts.com | http://diagnosingbarretts.com. |





The objective of these American and British patient use websites is to provide information on these illnesses, their diagnostic method, and the potential contribution of optical biopsy.

There one can find patient testimonials, specialist search engines by country, as well as treatment options for these pathologies.

Endomicroscopy with Cellvizio® has the benefit of being able to reassure the patient in the numerous cases where the cells are healthy, because it eliminates an anxiety-provoking wait of several days to several weeks for the pathology examination results.

The sites are therefore an aid for the patients and their family, but also very useful for general practitioners and specialists.

### 8.3.2 Regulatory environment

The national competent authorities and notified bodies develop, validate, and check that the standards and regulations are applied by manufacturers of medical devices according to their classification.

Within the European Union and partner countries, Mauna Kea Technologies works with G-Med on the CE marking of its class IIa devices.

The Food and Drug Administration (FDA) in the USA, the CFDA in China and MHLW in Japan are the main authorities that validate the compliance of its devices.

In April 2014 Mauna Kea Technologies obtained a double authorization: one Class 1 authorization for the use of Cellvizio® technology and one Class 2 (NINSHO) authorization for the endoscopic use of the Cellvizio® confocal miniprobes. Both relate to all of the current clinical indications of Cellvizio®: gastroenterology, urology, and pulmonology.

Each time it significantly modifies its devices, whether in technical terms or in terms of their potential use, including any new application, Mauna Kea Technologies files an application with the competent authority. In the United States the Company has obtained 16 regulatory 510(k) agreements from the Food & Drug Administration. In 2019, the Company obtained the first authorization from the FDA for the use of the AQ-Flex™ 19 confocal miniprobe through the use of transbronchial needles with existing bronchoscopes and bronchoscopic accessories.

### 8.3.3 Market access environment

Once it has registered its technology with the competent authorities in countries where its devices are to be marketed, the Company must enquire about reimbursement codes and rates so that patients can be covered and practitioners can be reimbursed once the medical treatment has taken place.

In March 2012, the Company obtained the creation of three so-called CPT® codes of Category I, specifically granted by the American Medical Association (AMA) for endomicroscopy in the upper digestive tract. The creation of these codes is a strong recognition of the interest of doctors and the healthcare system in optical biopsy and in the products of Mauna Kea Technologies in the United States. In March 2015, a CPT of Category III was obtained, for the use of endomicroscopy in bile ducts. Cellvizio® procedures can now be reimbursed by public and private insurance companies in the United States thanks to the CPT codes obtained. The inclusion of the procedure by Medicare and a number of payers relates to some 100 million American citizens. In November 2016, Medicare published the 2017 reimbursement rates, and the rates for the Optical Endomicroscopy code rose 131% for hospitals and 86% for ambulatory surgical centers, a major event for the Company. In this context, Mauna Kea Technologies launched new marketing initiatives in the United States to accelerate the adoption of the technology in the United States: the consignment of the Cellvizio® and Confocal Miniprobe® systems according to contractual agreements with healthcare institutions and users and with fee-for-service billing. In 2019 these repayments were all maintained or even slightly increased.

At the same time, initiatives have been taken to obtain reimbursement codes to use Cellvizio® in various European countries, and certain East Asian countries.

Data from clinical trials is analyzed for medico-economic evaluation of the diagnostic procedures taking into account current practices and the impact of the introduction of Cellvizio® in patient management. These analyses will help us expand into other countries. Studies conducted by the Company have enabled the development of medico-economic models demonstrating the clinical and economic benefits of the technology. In comparison with so-called standards, including conventional biopsy, some models and publications have concluded that it offers the advantage of avoiding taking physical biopsies on areas identified as healthy using digital optical biopsy; taking into account for example that 90% of physical biopsies are negative in screening for Barrett's Esophagus, that corresponds to several million tissue removals which could be avoided, and potential savings for healthcare systems of several hundreds of millions of euros, as presented during the Symposium organized by the Company with around a hundred experts in digestive pathology at the end of 2015, which can be found in the book, "Endomicroscopy in digestive pathology". Furthermore, applied to pancreatic cysts as a diagnosis tool, endomicroscopy allows practitioners to avoid operating on patients who do not require it but who would have undergone it on a conservative basis. The use of endomicroscopy ithus reduces the overall cost by avoiding major and costly surgery.

In 2017, a new study published in Endoscopy International Open, conducted under the direction of Claude Le Pen, Professor of Healthcare Economics at l'Université Paris-Dauphine, demonstrated the potential for substantial reduction in clinical costs in France through the use of Cellvizio® in the diagnosis of pancreatic cysts. Entitled "A Health Economic Evaluation Of Needle-Based Confocal Laser Endomicroscopy For The Diagnosis Of Pancreatic Cysts", this evaluation carried out from the point of view of the public insurer and taking into account the official rates of the French Heatlh Insurer shows the economic interest in diagnosing benign cysts through fine needle puncture confocal endomicroscopy (EUS-FNA+nCLE), compared to the ultrasound-guided biopsy (EUS-FNA) which is the standard method today. Thus the Cellvizio® fine needle puncture provides significant cost savings by reducing the risk of misdiagnosis through better accuracy, namely:

A 23% reduction in the total number of surgical procedures, associated with a 13% reduction in clinical costs (public sector) and 14% (private sector);
A reduction in the number of surgical procedures helping to save the life of 4 out of 1,000 patients.

This is a dominant strategy combining mortality gains and cost of care reduction in this indication.

### 8.3.4 Economic environment

Convinced that, in France it must encourage the emergence from start-up to success to generate economic value and jobs, the French government created the Initiative French Tech at the end of 2013. "French Tech" means all those who work in or for French start-ups in France or abroad: entrepreneurs primarily, but also investors, engineers, large groups, associations, media outlets, public operators, research institutes committed to the growth of start-ups on the one hand and their international influence on the other.

The philosophy of French Tech is: to rely on initiatives of the members of French Tech to develop what already exists, and to create a snowball effect. It is a shared ambition, driven by the State, but supported and built with all of the players.

In the vocabulary of French Tech, a start-up is a young company with a global ambition in search of an economic model that will ensure strong and rapid growth or taking risks through exploring new products or services, those which succeed become very rapidly international enterprises, with several hundred, even thousands, of employees.

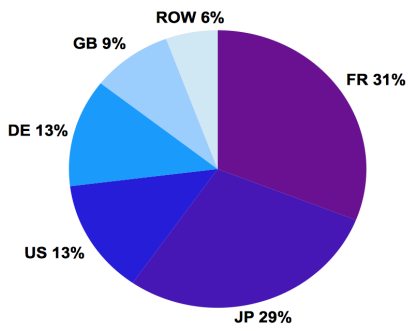
It was thus completely natural that since 2014, Mauna Kea Technologies has been an active player in French Tech, with its Founder and Chairman, Alexandre (Sacha) Loiseau, regularly participating in conferences, open days, and other initiatives.

### 8.3.5 Subcontracting and suppliers

Mauna Kea Technologies maintains privileged relationships with its suppliers. It worked during this year with 138 suppliers for its production and research and development purchases, particularly in the optical, electronic and mechanical categories. 59% of suppliers used were French, i.e. a slight increase compared to 2018 (54%).

**59% of French suppliers**

The Company uses subcontracting for the integration of Cellvizio® electromechanical boxes, the manufacture of certain probes as well as the translation of user documents with the same French, Japanese and British subcontractors for many years.




The main countries it works with are Japan and France with respectively 29% and 31% of the purchase volume of raw materials and services for production and research/development, then the United States and Germany with 13%. It is noted that these trends have been relatively stable for several years, with priority given to building long-term supplier partnerships. These countries are not deemed to be at risk with respect to work conditions. Its principal supplier, which represents 31% of production purchases, is a shareholder of the Company; a contract was entered into with it for the transfer of probe production.

Suppliers are monitored throughout their relationship with Mauna Kea Technologies: from the sourcing phase, where strategic suppliers are selected based on objective criteria shared by all, to monitoring their performance through an annual evaluation of the 50 most critical suppliers and to a supplier audit program conducted by auditors trained in the exercise and compliance with standards and regulations. In 2019, six supplier audits were carried out.

Mauna Kea Technologies has been tracking supplier payment indicators for several years. In 2019, the average payment term was 45 days, down compared to 2018 (-2 days), 68% of invoices were paid late (59% in 2017), and the average delay was 17 days, a sharp decline compared to 2018 (26 days). Nonetheless, we are continuing the work of the 2018 awareness campaign conducted with production and research and development suppliers to explain our accounting processes and to negotiate fairer terms of payment for all.

Finally, the good practices acquired thanks to ADEME's support in 2017 for more responsible purchasing continue to be applied on a daily basis, for example with an effort to select suppliers locally or the sharing by all employees of the same ethics.

### 8.3.6 Educational environment

The Company has a partnership policy with certain schools. The Company regularly receives students of different levels at its premises to present its activities. These days of exchanges make it possible for the Company to present open internships, but also for the students to present their projects and their professional aspirations.

In the same way, the Company works very closely with the Université Technologique de Compiègne, in the context of exchanges with former students.

Mauna Kea Technologies also contributes to the professionalization program offered by business schools, engineering schools and universities (Specialized Masters), providing internships or work-study placements to students who are integrated into Company functions (quality, clinical affairs, research and development).

### 8.3.7 Industrial and academic environment

Mauna Kea Technologies is growing in a competitive sector; it therefore emphasizes protection of its confidential and proprietary information, in order to ensure its technological advancement. The Company does, however, promote interactions with its technological environment, in the framework of partnerships and collaborative projects, but also with players in the market in which it operates, in the framework of its strategic development.

Various types of confidential information are communicated by the Company: scientific, technical, financial or clinical data. Such exchanges are systematically covered by confidentiality agreements.

Models, specifically developed in accordance with the needs of Mauna Kea Technologies, are utilized in order to maintain the confidentiality of information exchanged with the various partners. They are mainly utilized outside of any contractual partnership.

### 8.3.8 Ethical environment

Fairness and ethical business conduct are part of the basic principles of Mauna Kea Technologies' activities. Clinical affairs comply with the rules of ethical business conduct through the anonymity of patient data used during clinical trials, and the software incorporated into the products is developed in compliance with the ISO Standard 62304 and the GDPR.

Pursuant to the transparency laws (Sunshine Act) that govern relations between industry and healthcare professionals, Mauna Kea Technologies has set up internal processes for gathering the necessary information and raising awareness among its personnel who are in contact with healthcare professionals.

In France, for example, within the framework of the Bertrand Act of May 29, 2011 as amended in 2016 relating to the transparency of benefits granted by businesses producing or marketing products which have a healthcare-related or cosmetic end use for humans, the following information must be made public:

The existence of agreements entered into with health professionals and other similar persons (with the exception of agreements governed by Articles L. 441-3 and L. 441-7 of the French Commercial Code),
The total benefits granted for which the amount is equal to or greater than €10.

Such information is centralized on a single website which is managed by the Ministry of Health.

Lastly, the Company has organized every year since 2009 the ICCU event (International Conference of Cellvizio® Users). 2015 saw the seventh edition of this event. In response to the success of this event, an independent scientific committee was created for the selection and revision of the scientific works submitted for public presentation.

Thus, the different presentations or posters were selected in full independence, under the aegis of a Scientific Secretariat comprised of 18 experts representing the various specialties, which may be found during this event.

An education committee was also set up to coordinate the specialized or "Post-Graduate Course", intended for physicians wishing to improve their skills, particularly in the interpretation of confocal endomicroscopic images.

Changes to the Code of Ethics of the medical devices industry mean that Mauna Kea Technologies can no longer organize this event. On the other hand, the creation in the United States in October 2016 of a Learned Society: "International Society for Endomicroscopy – IS4E" by a group of practitioners who advocate for technology and its benefits to patients will help to continue fruitful exchanges within the scientific community and users (www.IS4E.org). Two events were organized in 2018 by this new Company to discuss setting up annual conferences dedicated to endomicroscopy.

Finally, the Company scrupulously complies with the rules of independence with respect to healthcare professionals, in order to guarantee that their product-purchasing decisions will always be made in the interest of the patient, thanks in particular to a code of conduct. The latter defines the conduct to be adopted vis-à-vis healthcare professionals, based upon the latest versions of the Advamed and MEDTECH codes of ethics published in 2016 with effect from January 1, 2017 regarding relationships between industry and healthcare professionals. The single international code for all staff is expected to be available in 2018 in both English and French. In this respect, compliance training for new hires is already being disseminated.

### 8.3.9 Working environment at Mauna Kea Technologies

**Job creations**

In addition to the jobs created directly by Mauna Kea Technologies, which had 72 employees at its head office in France at the end of 2019 and 30 in its subsidiary and representation offices, the Company has forged a network of privileged relationships with certain French and European but also Japanese suppliers, with which it develops, designs, and manufactures its products.

**Employment and integration of disabled workers**

The Company has set up a partnership with a Workforce Support Service Establishment (ESAT); it thus employs handicapped workers in printing assignments.

With respect to 2019, this partnership corresponded to 0.03 disabled worker full-time equivalents (or beneficiary units).

In addition, a poster campaign was carried out within the company to raise employee awareness of diversity.

**Anti-discrimination and gender policy**

The Company does not discriminate in hiring, whether in terms of origin, religion, age, or gender: all profiles are examined with equal scrutiny. We base our decisions exclusively on what profile is best suited to the competencies being sought.

Policy of gender parity and gender distribution

| Scope France | 12/31/2019 | 12/31/2018 | Change |
|---|---|---|---|
| Women executives | 46% | 38% | +8. |

The proportion of women executives has increased this year to 46% of the Company's workforce. The mostly male workforce is explained by the technical and mechanical orientation of the Company's core business. Mauna Kea Technologies employees mainly have technical profiles and therefore we have a predominance of male employees as a result.

**Professional Equality Index**

Mauna Kea Technologies has been subject, in France, to the calculation of this index since 2020.

This index is comprised of 4 indicators:

1. Gender compensation gap (maximum 40 points)
   > favorable gap for women of 2.2%, score obtained: 37 points;

2. Difference in rate of increase between women and men (maximum 35 points)
   > favorable difference for women, score obtained: 35 points;

3. Percentage of female employees increased upon return from maternity leave (maximum 15 points)
   > 100% of women increased following maternity leave in 2019, score obtained: 15 points;

4. Number of employees of the under-represented sex in the 10 highest paid positions (maximum 10 points)
   > 6 women and 4 men among the 10 highest paid positions, score obtained: 10 points.

The total score obtained was 97 points out of a maximum of 100.

This score is well above the average of French companies:

87 for companies with more than 1,000 employees;
85 for those with 250 to 1,000 employees;
83 for companies with 50 to 250 employees.
(source: https://travail-emploi.gouv.fr/)

**Employee assessment: The Performance and Development review**

More than a simple performance evaluation, the Performance and Development review aims to create a true dialog between the employee and the manager on development goals in the Company.

It begins by an employee balance sheet, prepared by the employee, who can broadly express what he or she likes about his/her position, his or her professional aspirations, and his or her development goals. It contains a paragraph, "Growing with the business", one of the four Company values, with the employee being given free rein to express him or herself.

The employee is then asked to express him or herself on his or her performance, its adequacy with respect to Company values, and a self-evaluation of competencies required for the position. He or she then proposes objectives for the following year.

The manager then holds an interview on the basis of this employee balance sheet, and analyzes the progress observed on the development areas set the preceding year. The manager also sets, in agreement with the employee, developmental actions for the following year, based on the gaps noted.
These actions are the basis for the Company's training plan.

**Compensation policy and its evolution**

Compensation is reviewed annually, in line with the employees' performance, assessed during Performance and Development reviews.

Taking into account the financial position of the Company, no profit sharing or incentive agreement has been put into place. Target-based bonuses are paid to all employees, with a portion linked to the Company's results, and the other on the basis of individual objectives.

Other compensation components:

Since its inception, the Company has implemented a supplemental health and retirement plan; mutual insurance is covered 70% by the employer, and the retirement plan, 100%. It is worth noting that the health insurance plan offers a very good level of coverage; Employees benefit from restaurant vouchers, with the employer assuming 53% of the cost. The face value is €9.

Lastly, all employees of Mauna Kea Technologies have for many years been connected with its performance through the allocation in France of Founders' warrants (BSPCE), Preference Shares connected with a Bonus Shares Grant or stock options in the United States.

**Labor relations**

Pursuant to order No. 2017-1386 of September 22, 2017 relating to the new organization of the social dialogue and following the end of the terms of office of the Works Council (CE), professional elections were held in October 2019 in order to set up the Social and Economic Committee (CSE).

The CSE is a single social dialogue body that replaces the three employee representation bodies: the Works Council (CE), the employee delegates (DP) and the health, safety and working conditions committee (CHSCT).

The organization of work hours is made on the basis of industry-wide agreements. (National Agreement of March 3, 2006 of the National Convention of Engineers and Executives in Metallurgy, and National Agreement of July 10, 1970, as amended, on Monthly Payment of Wages).

In 2019, the former CE met 9 times and the newly-elected CSE met 2 times.

**Health and safety**

The Company prepared a Single Document, in accordance with the legal provisions. This document was totally redefined in 2012, and a detailed action plan was implemented with the Committee for Health, Safety, and Working Conditions. It is monitored at each quarterly meeting of the Committee for Health, Safety, and Working Conditions.

It is worth noting:
No workplace accident occurred in 2019;
The Company owns an external defibrillator: the Company's First Aid workers have been trained in the use of this device, as well as around ten employee volunteers.

Employees who are exposed to contamination risks (because of frequent presence in hospitals) attend doctor visits, reinforced by blood-work analysis. Some employees also wear a radiation- protective dosimeter, to be worn in the operating room.

#### 8.3.10 Knowledge of our environment

Intelligence gathering involves the collection of information and the reinforcement of knowledge on the environment outside of the Company, making it possible for the Company to anticipate change and to assist in strategic decision-making. It is therefore a key factor in the survival and evolution of a business, especially in the field of innovation. Moreover, in a competitive sector, an effective Product Development activity goes beyond the four walls of a business and explores what is being developed and marketed on the outside. The intelligence-gathering activity thus also extends the objective of promoting in-house innovation.

In addition to participating in and actively contributing to multiple technical or medical conferences, in fields as varied as bio-photonics, the Computer-Vision, or medical and biomedical research, Mauna Kea Technologies uses its internal social networks (Google+, Slack) to disseminate and share, sometimes in near real-time, the information collected by its teams during such events.

This effort, which is complementary to and inherent in innovation, constantly trickles through all the Company's Product Development activities.

## 8.4 Environmental Footprint

#### 8.4.1 To reduce the environment footprint of products all throughout the life cycle

Starting from the product design phase, the Company takes into account all European regulations pertaining to the environment (for example, REACH, ROHS, DEEE, etc.) whose objective is to:

Limit waste and its hazards;
Promote reuse and recycling;
Improve conditions for disposal and control;
Limiting or prohibiting the use of certain hazardous materials.

These regulations and their requirements are completely integrated into the Company's quality-control system. Specific procedures, under the joint responsibility of Quality and R&D engineers, have been established in order to guarantee that no substance, which is hazardous to the environment, is incorporated into its products.

A REACH and RoHS regulations monitoring process has been implemented since 2014. Mauna Kea Technologies now systematically requires new documentation of the supplier's commitment to comply with these standards. In 2017, in view of the many changes in the REACH regulation, a new in-depth review of all the parts included in the nomenclature of our products was conducted by a working group composed of an R&D engineer specialized in medical device vigilance, a regulatory manager and a buyer. The suppliers were

again surveyed in order to prove their compliance with the REACH and RoHS regulations. The Company is now compliant with RoHS regulations and has obtained proof of REACH compliance for 98% of its product components.

In addition, Mauna Kea Technologies called upon an approved eco-entity (Recylum) for the recycling of its products at the end of their useful life. Products reaching the end of their useful life are collected by the company, sorted and stored with a view to recycling, as required by the regulations in force.

Finally, thanks to the support of ADEME in 2017 and a stated desire to reduce our environmental impact, new packaging has been designed for one of our products and the share of recyclable materials increased from 87% to 98% of the total weight. Previously, some of the product and packaging was shipped from the United Kingdom. The logistics scheme has been simplified and greenhouse gas emissions have decreased by 97% for the packaging of this product.

### 8.4.2 Reduce the Company's environmental footprint

**Production and marketing activities**

The activities of Mauna Kea Technologies do not implement hazardous products or contribute to any significant pollution. Mauna Kea Technologies has "clean" manufacturing, based upon optical and mechanical processes, which use very little chemical product.
With respect to waste management, the soiled residue from production (disinfecting wipes, gloves, adhesive residues, etc.) presenting an infectious risk are stored in a special container. This container is collected by a specialized company (EDC, GC Group), which reduces the infectiousness of the waste to the level of household garbage.

The Company is committed to reusing products at the end of their useful life for trials and tests, for example, destructive tests or durability tests on our probes, or by recovering components for the production of models or prototypes during new product design.

**Mauna Kea Technologies is committed to controlling the use of resources**

Taking into account the number of employees and of its operations, the Company has little impact on its environment. Nevertheless, daily actions are performed in order to limit this footprint.

For example, in 2012, it renewed its pool of printers, and introduced a badge-recognition system, which enabled it to limit unnecessary printing and paper waste. It also implemented selective sorting in all offices at the beginning of 2017 and made all employees aware of the process.

**Greenhouse gas emissions**

The Company has a fleet of three low-emission vehicles with CO2 emission rates below 130 gCO2/km, and a scooter.

The electrical consumption is as follows: it was 146,501 kWh in 2019 versus 138,125 kWh in 2016 for the main site, respectively 9,479 kg CO2 equivalent versus 8,937 kg CO2 equivalent (*).

(*) 64.7 g of CO2 equivalent per kWh, source ADEME Electricity 2016 - average mix.

The Company has also identified significant greenhouse gas emissions in view of its activity: Transported merchandise upstream and downstream of the logistics supply chain, business travel as well as work/home commutes. A more in-depth study must be conducted to quantify these various items and to analyze the possible drivers to reduce greenhouse gas emissions.

# SECTION 9
# 9. REVIEW OF THE RESULTS AND FINANCIAL POSITION

The reader is invited to read the following information on the Group's financial position and earnings with the Group's consolidated financial statements prepared in accordance with IFRS standards for the year ended December 31, 2019, and to refer to the notes to the 2018 consolidated financial statements, as contained in 2020 of this Universal Registration Document. The 2016 and 2017 financial statements can be viewed on the Group's website: www.maunakeatech.com.

## 9.1 Overview

### 9.1.1 Consolidated financial statements

Pursuant to EU Regulation No. 1606/2002 of July 19, 2002, the 2019 consolidated financial statements of Mauna Kea Technologies, approved by the Board of Directors on April 27, 2020, were prepared in accordance with the IFRS standards as adopted in the European Union.

### 9.1.2 Operations of the Group

The reader is invited to read the description of the Group's activity, presented in 66 "Overview of activities" of this Universal Registration Document.

### 9.1.3 Pro-forma financial reports

N/A.

## 9.2 Results analysis

Simplified consolidated income statement

| Consolidated data audited in €K | At December 31 | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Total sales of "equipment" | 2,301 | 2,683 | 3,101 |
| Total sales of "consumables" (probes) | 4,122 | 2,812 | 2,397 |
| Total sales of "services" | 1,007 | 1,265 | 1,188 |
| **Total sales** | **7,431** | **6,760** | **6,687** |
| Other income | 1,077 | 1,141 | 1,144 |
| **Total of revenue** | **8,509** | **7,901** | **7,831** |
| Cost of sales | (2,260) | (2,058) | (2,129) |
| Gross margin | 70% | 70% | 68% |
| **Total operating expenses** | **(21,537)** | **(19,899)** | **(17,541)** |
| Other operating income and expenses | 0 | 0 | 0 |
| **Operating Profit (Loss)** | **(13,028)** | **(11,998)** | **(9,710)** |
| **Profit before tax** | **(15,272)** | **(12,785)** | **(10,245)** |
| **Profit / (loss)** | **(15,272)** | **(12,785)** | **(10,245)** |

### 9.2.1 Sales and other operating income

Financial Year 2019 sales

| (in € thousands) – IFRS | 2019 | 2018 | Change % |
|---|---|---|---|
| 1st quarter | 1,716 | 1,042 | 65% |
| 2nd quarter | 2,221 | 1,665 | 33% |

| | | | |
|---|---|---|---|
| 3rd quarter | 1,803 | 1,933 | (7%) |
| 4th quarter | 1,691 | 2,120 | (20%) |
| **Total Sales** | **7,431** | **6,760** | **10%** |

Financial Year 2019 sales by category

| **(in € thousands) – IFRS** | **2019** | **2018** | **Change %** |
|---|---|---|---|
| Systems | 2,301 | 2,683 | (14%) |
| Consumables | 4,119 | 2,812 | 46% |
| *including "pay-per-use"* | *1,682* | *890* | *89%* |
| Services | 1,011 | 1,265 | (20%) |
| **Total Sales** | **7,431** | **6,760** | **10%** |

Full-year 2019 sales amounted to €7.4 million, a 10% increase on the previous year. Increased sales for full-year 2019 were driven by a 47% increase in sales of consumables, partially offset by a 14% reduction in income from systems and a 20% reduction in sales of services throughout the period. Total sales of consumables were driven by an 89% increase in "pay-per-use" sales following an increase in the installed base successfully initiated during 2018. Sales of consumables relating to the "pay-per-use" program accounted for 41% of total sales of consumables in 2019, versus 32% in the previous year.

Financial Year 2019 Sales by Geography with split by activity (Clinical/Preclinical)

| **(in € thousands) – IFRS** | **FY 2019** | **FY 2018** | **Change** |
|---|---|---|---|
| **United States & Canada[18]** | **3,434** | **3,582** | **(4%)** |
| Clinical | 3,399 | 3,181 | 7% |
| Preclinical | 35 | 400 | (91%) |
| **Asia-Pacific** | **2,562** | **1,599** | **60%** |
| Clinical | 2,509 | 1,407 | 78% |
| Preclinical | 53 | 191 | (72%) |
| **EMEA** | **1,153** | **1,544** | **(25%)** |
| Clinical | 967 | 1,001 | (3%) |
| Preclinical | 186 | 543 | (65%) |
| **Latin America** | **282** | **36** | **683%** |
| Clinical | 282 | 36 | 683% |
| Preclinical | 0 | 0 | n/m |
| **Total Clinical Sales** | **7,157** | **5,626** | **27%** |
| **Total Pre-clinical Sales** | **273** | **1,135** | **(76%)** |
| **Total Sales** | **7,431** | **6,760** | **10%** |

### 9.2.2 Operating expenses

| Consolidated data audited in €K | 2019 | 2018 | Change |
|---|---|---|---|
| Cost of sales | (2,260) | (2,058) | 10% |
| Gross margin | 70% | 70% | |
| Research & Development | (3,160) | (4,653) | (32%) |
| Sales & Marketing | (8,978) | (9,097) | (1%) |
| Administrative expenses | (6,187) | (3,953) | 57% |
| Share-based payments | (952) | (138) | 590% |
| **Total operating expenses** | **(21,537)** | **(19,899)** | **8%** |

**Cost of products sold and gross margin**

The cost of goods sold came to €2,260 thousand for 2019 versus €2,058 thousand for 2018, representing 30% of sales for each year. Gross margin was 70% in 2019 and 2018.

[18]Sales in the United States and Canada were previously reported with sales for the Latin America region under the Americas heading.

**Research and Development Costs**

Throughout financial year 2019, the Research and Development team continued its work on the next generation of systems.

In 2019, Research and Development expenses amounted to €3,160 thousand, versus €4,653 thousand for 2018.

In 2019, the annual portion of capitalized development expenses was €838 thousand. The Company maintains a high level of R&D expenses mainly attributed to research and development in the fulfillment of projects led from several years.

**Marketing and Sales Costs**

Marketing and Sales expenses are currently the largest overhead. They reached €8,978 thousand in 2019 versus €9,097 thousand in the 2018 financial year.

In marketing, at year-end 2019 the Group had a team of 9 people covering the activities of Operational Marketing (France, Rest of Europe, United States and Asia), the Systems and Probes product development activity, Clinical Affairs and marketing communication.

Sales are made directly in France, Germany and the United States, and through distributors in the rest of Europe and in Asia.

At the end of 2019, the sales teams were comprised of:

- 6 people in the EMEA region;
- 18 people in the United States;
- 2 people in China.

In total, at the end of 2019, the Group had a sales force of 26 people led by a sales manager for the EMEA and APAC regions, and by two regional sales managers for the United States.

**Administrative expenses**

Administrative expenses were up by 57% on 2018, from €3,953 thousand in 2018 to €6,187 thousand in 2019. This increase is driven by the impact of investments made in the second half of 2018 to strengthen the management team on the full year.

**Share-based payments**

As with previous financial years, the Group continued to issue stock options to its US employees, and also warrants (BSA) to its independent board directors. As the Group is no longer allowed to issue founders' warrants (BSPCE), in 2016 the Group implemented a free preferred share plan whose terms and conditions were voted on and approved by the shareholders at the Annual General Meeting of October 5, 2018. The share-based payments in 2019 amounted to €952 thousand, compared with €138 thousand in 2018.

### 9.2.3 Composition of net income

Operating expenses amounted to €21,537 thousand for the full year, compared with €19,899 thousand in 2018, representing an 8% increase, whose main contributing factor was the increase in sales and marketing expenses.

As a result of this increase and the 10% increase in sales, the operating loss for 2019 was €(13,028) thousand, compared with €(11,998) thousand.

After taking into account a financial loss of €(2,244) thousand for the year to December 31, 2019, compared with a loss of €(786) thousand at December 31, 2018, the Company's net loss comes to €(15,272) thousand, compared with a net loss of €(12,785) thousand for the year ended December 31, 2018.

### 9.2.4 Corporation tax

In view of the losses recorded in the last three financial years, the Group has not recorded any income tax expense.

Deferred tax assets are only recognized to the extent that probable future profits will be sufficient to absorb the losses carried forward. In view of its stage of development, the Company does not recognize net deferred tax assets.

### 9.2.5 Earnings per share

The loss per issued share (weighted average number of outstanding shares during the year) came respectively to €0.60 and €0.51 per share for the financial years ended December 31, 2019 and 2018.

## 9.3 Balance sheet analysis

### 9.3.1 Non-current assets

| Consolidated data audited in €K | 2019 | 2018 | Change |
|---|---|---|---|
| Intangible assets | 2,343 | 1,838 | 27% |
| Property, plant, and equipment | 1,956 | 1,985 | (1%) |
| IFRS 16 rights of use | 1,370 | n/a | n/a |
| Non-current financial assets | 173 | 133 | 30% |
| **Non-current assets** | **5,842** | **3,956** | 48% |

Non-current assets were €5,842 thousand at December 31, 2019, 48% more than the €3,956 thousand at December 31, 2018.

Non-current assets consist of IFRS 16 rights of use, property, plant and equipment and intangible assets, and non-current financial assets.

The increase in this item is due in part to the increase in intangible assets due to the capitalization of the GEN 3 development costs for €838 thousand, and also to the impact of the 1st application of IFRS 16 on January 1, 2019 for €1,432 thousand. This standard mainly covers real estate leases in France and the USA as well as motor vehicle leases.

The detailed impact of the first-time application of this standard on the consolidated financial statements is shown in Notes 1.1 and 4 of the consolidated notes in Section 20.1 20.1this Universal Registration Document.

Non-current financial assets include only the security deposits paid under operating leases.

The breakdown of non-current financial assets can be found in Note 5 to the consolidated financial statements, in Section 20.120.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2019" of this Universal Registration Document.

### 9.3.2 Current assets

| Consolidated data audited in €K | **2019** | **2018** | **Change** |
|---|---|---|---|
| Inventories and work in progress | 2,592 | 2,456 | 6% |
| Trade receivables | 2,444 | 1,643 | 49% |
| Other current assets | 2,701 | 3,019 | (11%) |
| Current financial assets | 59 | 64 | (8%) |
| Cash and cash equivalents | 9,982 | 8,623 | 16% |
| **Current assets** | **17,778** | **15,806** | 12% |

Current assets amounted to €17,778 thousand at December 31, 2019, versus €15,806 thousand at December 31, 2018.

Negative net cash flows relating to operating activities are financed with the Group's cash. This translated into a decrease in the outstanding amount of cash and current financial instruments, which stood at €10.0 million at December 31, 2019, versus €8.6 million at December 31, 2018.

Cash and the outstanding amount of cash represented 56% of current assets at December 31, 2019.

As a beneficiary of the EC SME regime, the Research Tax Credit receivable was affected only by the change in research and development expenses eligible for the CIR during the years in question.

The Research Tax Credit receivable at December 31, 2019 was €2,138 thousand versus €2,186 thousand at December 31, 2018, corresponds to the 2018 and 2019 CIR. (See Note 7.2 to the consolidated financial statements presented in Section 20.1 "20.1financial statements prepared according to IFRS for the financial year ended December 31, 2019" of this Universal Registration Document).

### 9.3.3 Equity

| Consolidated data audited in €K | 2019 | 2018 | Change |
|---|---|---|---|
| Share capital | 1,223 | 1,008 | 21% |
| Share premium | 98,257 | 91,753 | 7% |
| Reserves | (84,130) | (72,072) | 17% |
| Foreign currency translation on reserve | 176 | 74 | 138% |
| profit/(loss) | (15,272) | (12,785) | 19% |
| **Total of equity** | **253** | **7,979** | **(96%)** |

The net changes in Group equity are mainly due to the annual deficits recorded in 2018 and 2019, and to the increase in share premiums following capital increases.

The deficits recorded during the two financial years studied show the efforts that the Group devoted in particular to Research and Development programs as well as to the completion of clinical studies and marketing actions. They also take into account the IFRS 2 expense relating to the granting of founders' warrants (BSPCEs), share warrants (BSAs), and bonus preferred shares and stock options to employees, corporate officers and partners of the Group. This expense was offset by a positive variance in shareholders' equity in an equivalent amount.

### 9.3.4 Non-current liabilities

| Consolidated data audited in €K | 2019 | 2018 | Change |
|---|---|---|---|
| Non-current liabilities | | | |
| Long-term loans and borrowings | 15,499 | 6,457 | 140% |
| Non-current provisions | 299 | 422 | (29%) |
| **Total of non-current liabilities** | **15,799** | **6,879** | **130%** |

Long-term loans and borrowings at December 31, 2019 include the 1st instalment of the European Investment Bank (EIB) loan for €10.6 million, repayable aid granted by BPI (formerly OSEO) for €3.4 million, as well as IFRS 16 lease liabilities for €0.9 million.

Refer to Note 11 to the consolidated financial statements shown in Section 20.1 of 20.1this Universal Registration document.

### 9.3.5 Current liabilities

| Consolidated data audited in €K | 2019 | 2018 | Change |
|---|---|---|---|
| Short-term loans and borrowings | 1,916 | 600 | 219% |
| Trade payables | 2,275 | 2,087 | 9% |
| Other current liabilities | 3,380 | 2,216 | 53% |
| **Total of current liabilities** | **7,570** | **4,904** | **54%** |

This balance sheet item groups together short-term loans and borrowings to third parties, short-term financial debt (including €1.4 million related to the sale of the Research Tax Credit receivable) as well as debts to employees and social security bodies.

# SECTION 10
# 10. CASH AND CAPITAL

## 10.1 Information on the Group's capital, liquid assets and sources of financing

See also Notes 9, 10 and 11 to the consolidated financial statements prepared in accordance with IFRS, appearing in 20.120.1 of this Universal Registration Document.

Cash and cash equivalents include cash on hand only. This cash on hand serves to finance the Company's activities, especially its research and development expenses and its marketing and sales expenses.

Since its creation in 2000, the Company has financed itself by the issue of new shares (shares called "O ordinary shares" and shares called "P preferred shares"), as well as by significant conditional advances granted by OSEO and COFACE. Since 2011, the Company's funding has come primarily from the following sources:

- its IPO in July 2011 raised €56.5 million gross, or €51.6 million net after deducting transaction costs;
- advances received under the PERSEE project for a cumulative amount of €2.9 million;
- a private placement with nine investors in May 2015 for a total gross amount of €4.7 million, i.e. €4.5 million net of transaction costs;
- drawdowns between March and December 2015 on two equity financing lines (PACEO I & PACEO II), totaling €3.2 million net;
- a capital increase in July 2016 for a gross amount of €4.4 million, subscribed by a limited number of investors operating in the healthcare sector;
- drawdowns between November 2016 and December 2016 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €2.5 million net;
- a €9.0 million bond issue with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector. This financing was comprised of two debt tranches, drawn in February 2017 for €4.0 million and in May 2019 for €3.0 million. This bond was fully repaid on June 28, 2019 for €10.7 million, including early repayment fees;
- drawdowns between January 2017 and December 2017 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €15.5 million net;
- drawdowns in January 2018 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €3.8 million net;
- a €7.5 million capital increase reserved for Johnson & Johnson Innovation Inc. in December 2019 through the issue of 5,357,142 new ordinary shares with a nominal value of €0.04 each, for an issue price of €1.40;
- a €22.5 million financing in June 2019 with the European Investment Bank (EIB). This term financing repayable in 5 years, is comprised of 3 tranches. The first tranche of this financing was received in July 2019 for €11.5 million.

Summary of drawdowns by Kepler Cheuvreux

| | BSA 2016-2 | BSA 2017-1 | BSA 2017-2 |
|---|---|---|---|
| Date of General Meeting | May 4, 2016 | May 3, 2017 | May 3, 2017 |
| Date of Chairman's decisions | Nov 18, 2016 | Sept 19, 2017 | Dec 1, 2017 |
| Number of authorized share warrants (BSA) | - | - | - |
| Total number of BSA issued | 1,850,000 | 2,100,000 | 2,250,000 |
| Total number of shares that may initially be subscribed for<br>of which the number that may be subscribed by corporate officers | 1,850,000<br>0 | 2,100,000<br>0 | 2,250,000<br>0 |
| Number of beneficiaries who are not corporate officers | 1 | 1 | 1 |
| Start date for exercise of the BSA | Nov 18, 2016 | Oct 6, 2017 | Dec 1, 2017 |
| BSA expiration date | Nov 18, 2018 | Oct 6, 2018 | Dec 1, 2018 |
| BSA issue price | €3.0000 | | |
| Number of shares subscribed at December 31, 2018 | 1,850,000 | 2,100,000 | 2,050,000 |
| Cumulative number of BSA canceled or invalid as of December 31, 2019 | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| BSA remaining at December 31, 2019 | 0 | 0 | 200,000 |
| Number of shares that may be subscribed for as of December 31, 2019 | 0 | 0 | 200,000 |

In accordance with the terms of the agreement, Kepler Cheuvreux, acting as financial intermediary and guarantor of the transaction, committed to subscribe to shares, on its own initiative, following a timetable over a maximum period of 24 months. The shares will be issued based on a volume-weighted average share price over the two trading days preceding each issue, minus a maximum discount of 6.5%.

The PACEO financing contract with Kepler Chevreux matured on December 4, 2019 and has not been renewed.

Changes in the composition of the share capital during the year

| | Number of shares | Nominal value (euros) | Share capital (euros) |
|---|---|---|---|
| Shares comprising the share capital at the beginning of the financial year | 25,201,338 | 0.04 | 1,008,053.52 |
| Reserved capital increase | 5,357,142 | 0.04 | 214,285.68 |
| Preference shares | 13,260 | 0.04 | 530.40 |
| Shares comprising the share capital at the end of the financial year | 30,571,740 | 0.04 | 1,222,869.60 |

### 10.1.1 Capital financing

The following table summarizes the principal capital increases, in value, between the Company's creation date and December 31, 2019:

| Period | Gross Amounts raised (in €M) | Transactions |
|---|---|---|
| 2000 - 2001 | 1.7 | Seed capital |
| 2003 - 2006 | 7.2 | 1st round of financing |
| 2007 - 2008 | 22.5 | 2nd round of financing |
| 2000 - 2010 | 0.8 | Exercise of securities giving access to the capital (BSA, BSPCE) |
| 2011 | 56.5 | IPO in July |
| 2011-2014 | 2.4 | Exercise of securities giving access to the capital (BSA, BSPCE, stock options) |
| 2015 | 0.3 | Exercise of securities giving access to the capital (BSPCE, stock options) |
| 05.2015 | 4.7 | Capital increase |
| 2015 | 3.2 | Exercise of BSA by Société Générale (Paceo) |
| 2016 | 4.4 | Capital increase |
| 2016 | 2.5 | Exercise of BSA by Kepler Cheuvreux |
| 2017 | 15.6 | Exercise of BSA by Kepler Cheuvreux |
| 2018 | 3.8 | Exercise of BSA by Kepler Cheuvreux |
| 2019 | 214.3 | Reserved capital increase |
| Total | 339.9 | |

### 10.1.2 Financing through loans

On February 8, 2017, Mauna Kea Technologies announced a debt financing agreement with IPF Partners, containing two tranches for a total amount of €7.0 million, tranche A of which was exercised for €4.0 million in February 2017. The second tranche of €3.0 million has not been exercised.

In November 2018, the Company signed an amendment to the existing agreement, which included two additional tranches of debt, a first tranche of €5.0 million was available until the end of April 2019, and another tranche of €5.0 million was available until September 2019, both tranches being subject to predefined sales level conditions. At December 31, 2018, the Company fulfilled the conditions

necessary to raise the first tranche. In addition, the amendment modified the repayment schedule for tranche A exercised in February 2017, which would have begun from June 2019 and no longer from December 2018.

The loans would bear interest at an annual rate equal to 3 month Euribor +8.0%. The first loan tranche had a term of 5 years, with deferred principal repayment for the first 15 months. The second loan tranche had a term of 4 years, with deferred principal repayment for the first 12 months. The issuance of the warrants was subject to certain restrictive financial performance conditions, included in the terms and conditions of the agreement.

During the first half of 2019, the Company repaid in full the IPF bonds for €10.7 million (including early repayment fees).

At the same time, in June 2019, the Company signed a €22.5 million loan agreement with the European Investment Bank. The first tranche of €11.5 million available on condition of repayment of the IPF, while the subsequent tranches of €6 million and €5 million, will be available subject to the achievement of certain milestones, including the Company's commercial progress and its future equity financing activities.

The first tranche of €11.5 million was drawn down on July 3, 2019. This first tranche is repayable at the end of a 5-year period for both the capital and the capitalized interest at a fixed rate of 5%.

Tranche 1 is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of October 5, 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants may be exercised from this day until the twentieth anniversary of the issuance of the warrants, i.e. July 3, 2039.

On April 17, 2020, the Company obtained confirmation from the EIB that it could draw down the second tranche of €6,000 thousand pursuant to the contract.

On July 8, 2020, in accordance with the loan agreement as amended on June 19, 2020, the Company received Tranche 2 for €6 million. This second tranche will bear annual interest of 3% and capitalized interest of 4% payable in 5 years with the principal. Tranche 2 is also accompanied by the issue of share subscription warrants (BSA) entitling the holder, in the event of exercise, to subscribe to a maximum of 500,000 Company shares (i.e. 1.6% of the share capital on a non-diluted basis). These BSA warrants were issued on the basis of the twenty-fourth resolution adopted by the Combined General Meeting of July 2, 2020. The exercise price of the warrants is equal to the volume weighted average of the last three trading days preceding their issue, less a 5% discount. The BSA warrants may be exercised starting from their issuance and until July 3, 2039.

### 10.1.3 Financing by repayable advances

The Company has received three conditional advances that were the subject of an agreement with BPI France (formerly OSEO) as well as a loan from COFACE.

Summary of advances received:

| At Dec. 31, 2019<br>(in €k) | Gross amount granted | Gross amount cashed | Gross amount repaid | Discount effects | Amount remaining to be repaid |
|---|---|---|---|---|---|
| BPI France loans | 2,766 | | | 527 | 3,431 |
| **Total advances received** | **2,766** | | | **527** | **3,431** |

The repayable advances are described in Note 11 to the consolidated financial statements presented in Section 20.1of this Universal Registration Document.

### 10.1.4 Financing by the research tax credit

The Company benefits from the provisions of Articles 244 quater B and 49 septies F of the French General Tax Code relating to the research tax credit. The latter is recognized as other income.

The Research Tax Credit receivables relating to financial years 2018 and part of 2019 were sold in 2019 for a value of €1,442 thousand.

(Refer to Notes 1, 7.2 and 11.3 to the consolidated financial statements shown in 20.120.1 of this Universal Registration Document).

### 10.1.5 Off-balance sheet commitments

The Company's off-balance sheet commitments are described in Note 21 to the financial statements in accordance with IFRS as of December 31, 2019 appearing in 20.120.1 of this Universal Registration Document.

## 10.2 Cash flows variation

***Simplified consolidated cash-flow statements***

| Consolidated data audited in €K | At December 31 | |
|---|---|---|
| | 2019 | 2018 |
| Net cash flows from operating activities | (10,272) | (10,900) |
| Of which self-financing capacity | (12,105) | (10,874) |
| Of which change in WCR related to business activities | 1,834 | (26) |
| Net cash flows from investing activities | (1,416) | (1,246) |
| Net cash flows from financing activities | 13,036 | 3,299 |
| Net foreign exchange difference | 10 | 16 |
| **Change in cash** | 1,359 | (8,830) |

### 10.2.1 Cash flows from operating activities

The cash consumption relating to operating activities for the financial years ended December 31, 2019 and 2018 came to €10,272 thousand and €10,900 thousand respectively.

The cash consumption relating to operating activities decreased by 6% during the 2019 financial year. This decline is due to an improvement in WCR (+€1,834 thousand in 2019 versus -€26 thousand in 2018).

### 10.2.2 Cash flows relating to investment activities

Outside the "pay-per-use" model, the Company's production activity does not require major tangible fixed investments due to the use of subcontracting for part of the production. However, the final manufacturing tasks – assembly, control and validation – are performed in-house.

These investments in property, plant and equipment, in particular systems placed on consignment, demonstration devices, prototypes and office equipment, came to €525 thousand and €1,153 thousand respectively for the financial years ended December 31, 2019 and 2018.

On the other hand, the Company activated intangible assets in the course of the 2018 and 2019 financial years, mainly patent and other intangible asset expenses. In this respect, the Company invested €855 thousand and €101 thousand respectively for the 2019 and 2018 financial years. In 2019, research and development expenses primarily concerned the GEN III research and development, according to IAS 38 criteria.

### 10.2.3 Cash flows from financing activities

The Company recorded a cash flow related to financing activities of €13,036 thousand and €3,299 thousand for the 2019 and 2018 financial years.

In 2019, cash flows related to financing activities of €13,036 thousand mainly come from capital increases reserved for €6,792 thousand, the receipt of the 1st tranche of the EIB loan for €11,500 thousand, partially offset by the net repayment of the IPF bond for €6,053 thousand (including early repayment fees).

In 2018, the cash flow from financing activities of €3,299 thousand mainly came from BSA warrants exercised for €3,780 thousand.

## 10.3 Information on the repayable advance conditions and financing structure

See Notes 11.1 and 11.2 to the financial statements prepared under IFRS appearing in Section 20.1 20.1this Universal Registration Document.

## 10.4 Restriction on the use of capital

N/A.

## 10.5 Sources of financing required in the future

Refer to Section 4.3.1concerning liquidity risk in this Universal Registration Document.

# SECTION 11
# 11. INNOVATION, PATENTS, LICENSES, TRADEMARKS AND DOMAIN NAMES

Research and development costs are recognized in accordance with the IAS 38 standard. These costs are described in Note 1.4 to the 2019 consolidated financial statements presented in Section 20.1of this Universal Registration Document.

## 11.1 Innovation policy

Innovation is the Company's raison d'être: Its products and their applications reflect this positioning in the field of medical devices.

These products aim to contribute to the medical and research fields minimally-invasive real-time diagnostic imaging, which improves the service provided to patients and doctors but also paves the way for new medical or scientific practices, such as *in situ & in vivo* optical biopsies of tissues inaccessible for histopathological examination.

In terms of the Group itself, its innovative nature demonstrates both its ability to develop such products, but also to place itself within a corporate approach likely to promote new insight into problems relating to its activities. This ability appears transversally in the management, communication, product development, research and development, client relations, production, quality control and regulatory affairs, human resource management and administration.

The Group's innovation policy is made up of all the steps taken by the Group to ensure an approach that guides recruitment, personnel training, internal and external communication, working methods and coordination.

This policy encourages new ideas and ensures they are captured, notably through team work sessions, such as the Strategic Days, clinical meetings (MED), LAB meetings, Patent Brain Storming, and innovation competitions such as the "Hackfests", supported by continuous transversal (medical, scientific, technological) monitoring. The multidisciplinary nature of the representation of the Group's skills in these activities is an essential key to their success.

The R&D policy, the functioning of the teams concerned, as well as the R&D projects and fields on which the Company focuses, and the collaboration agreements entered into with third parties in the context of these projects, are described in Section 6.2.1The innovation strategy".

## 11.2 Patents and patent applications

### 11.2.1 Intellectual property protection policy

The Group's commercial success depends largely on its ability to protect its products, in particular by obtaining patents and maintaining them in force in France and the rest of the world. This is why the Group has established and maintains a continuous patent filing policy.

At the end of December 2019, the Group had a total of 40 inventions protected by patent registration, grouped in 34 families of separate patents. At that date, these 40 inventions had resulted in 248 patents being granted. Twenty-six patents are still under consideration.

To date the Company believes that its technology has not been used or copied illegally, in whole or in part, by third parties or competitors and is not aware of third parties challenging its intellectual property or its rights to use its intellectual property.

### 11.2.2 Nature and coverage of patents

These patents or patent applications accompany and reflect the Group's research and development work by their nature and the pace of the filings. Of course, they do not only concern the products currently marketed by the Company, but also cover complementary technologies that could form an integral part of its future products, in the clinical or research fields.

Among these families of patents or patent applications, seven of them result from partnerships or collaboration with academic partners such as the CNRS (French National Center for Scientific Research), the Paris Observatory, the Université de Rouen, the Université de Limoges and the Université Pierre & Marie Curie, and are jointly held with these institutions.

The Company is also the exclusive licensee of two patents relating, for the first (INSERM-APHP patent, or Endoscope, in the following table), to an endomicroscopic method specific to the Cellvizio, and for the second (patent of Université Denis Diderot - Paris 7 - or P7 in the same table) to *in vivo* high-resolution tomographic solutions for the human retina, not yet used. In both cases, the Company has filed (and obtained) in agreement with its co-contractors, several improvement patents for these technologies.

| Patent portfolio | | | | | |
|---|---|---|---|---|---|
| **Title** | **MKT number** | **Priority date** | **Acronym** | **Family Ref. No.** | **Title** |
| P7 | B | 04/01/99 | P7 | WO00/59368 | High resolution body observation device |
| Endoscopy | A | 09/15/98 | END | WO00/16151 | Organism observation device providing perfected observation quality |
| Afocal correctors | 1 | 12/28/01 | AFO | WO03/056378 | Confocal imaging equipment especially designed for endoscopy |
| Endoscope head | 2 | 12/28/01 | TEM | WO03/056379 | Miniaturized focusing optical head especially designed for endoscopes |
| Fluorescence Spectroscopy | 3 | 12/28/01 | TMS | WO03/060493 | Subsurface autofluorescence spectroscopy apparatus procedure |
| CVZ Fluo | 4 | 07/18/02 | CVF | WO2004/008952 | Fibered confocal fluorescence imaging apparatus and procedure |
| CVZ Fluo Divisionnaire (EU only) | 4 | 07/18/02 | CVF | EP 1986031 | High-resolution fibered confocal fluorescence imaging apparatus and procedure |
| Image processing | 5 | 07/18/02 | IMA | WO2004/010377 | Processing procedure of images acquired with a scope comprising multiple optical fibers |
| VCSEL | 6 | 12/20/02 | VCS | WO2004/066015 | VCSEL-based parallel confocal laser microscopy system |
| MEMS | 7 | 12/20/02 | TBL | WO2004/066016 | Confocal optical head, in particular miniaturized, with integrated scanner and confocal imaging system to operate the scope head |
| S probes (FR only) | 8 | 03/11/03 | CV2 | FR 2 852 394 | High-resolution fibered confocal fluorescence imaging apparatus and procedure |
| Super Reso | 9 | 12/31/03 | SUR | WO2005/073912 | Super-resolution procedure and system for confocal images acquired through an imaging scope, and device used to execute the procedure |
| Lent. Boule | 10 | 12/31/03 | LEB | WO2005/072597 | Miniature optical head with integrated scanner to acquire homogeneous confocal images, and confocal imaging system to operate the scope head |
| OCT-OA | 11 | 01/22/04 | DAT | WO2005/080911 | High-resolution in vivo lateral and axial tomographic system and procedure for the human retina |
| Wollaston | 12 | 01/22/04 | MES | WO2005/080912 | Device and procedure to measure fringe visibility in a Michelson interferometer, and eye examination system including said device |
| Active targeting | 13 | 01/22/04 | TOM | WO2005/079655 | Aiming procedure and device for eye examination, in vivo eye tomography system equipped with said device |
| Active targeting (CIP) | 13 | 01/22/04 | TOM | US 7,658,495 | Aiming procedure and device for eye examination, in vivo eye tomography system equipped with this device (Continuation in Part) |
| Velocimetry | 14 | 04/02/04 | VIT | WO2005/098474 | Blood flow rate measuring system and procedure |
| Multimarking | 15 | 04/16/14 | MTM | WO2006/000704 | Multimarking fibered fluorescence microscopic imaging system and procedure |
| 2Photons | 16 | 10/22/04 | 2PH | WO2006/045936 | Sample fibered multiphoton microscopic imaging procedure and system |
| Methylene blue | 17 | 03/31/06 | BDM | WO2007/118954 | Methylene-blue based fibered fluorescence microscopy |
| UHD probe | 18 | 05/05/06 | UHD | WO2007/128909 | High-sensitivity, high spatial resolution miniaturized optical head, especially designed for fibered confocal fluorescence imaging |
| Multiple probes | 19 | 05/12/06 | SMU | WO2007/132085 | Endoscopy procedure and device for the simultaneous observation of multiple areas of interest |

| | | | | | |
|---|---|---|---|---|---|
| Alveolar imaging | 20 | 08/17/06 | ALV | WO2008/020130 | In situ use of an in vivo fibered confocal fluorescence imaging system, in situ in vivo fibered confocal fluorescence imaging procedure and system |
| Mosaicing | 21 | 08/02/07 | MOS | FR 2 904 927 | Image mosaicing procedure, including motion distortion and tissue deformation cancellation option, for fibered confocal microscopy. |
| CVZ 2 | 22 | 10/11/07 | VZ2 | WO2009/053632 | Modular imaging device, module for the device and procedure performed by device |
| ERCP | 23 | 03/12/08 | RCP | US2009-0240143 | Optical procedure and probe for in vivo imaging of biliary or pancreatic duct mucosa, and procedure to selectively treat a biliary or pancreatic duct mucosa tissue sample |
| Automatic Calibration | 24 | 12/29/08 | CAL | WO2010/076662 | Image processing method and apparatus |
| OBF | 25 | 12/31/08 | OBF | US 8,267,869 | Multi-purpose biopsy forceps |
| Freeze algorithms | 26 | 01/30/09 | FRZ | WO2010/086751 | Processing method and system for images acquired in real-time by a medical device |
| Connector and polished probes | 27 | 03/12/09 | CON | WO2010/103406 | Connector for fibered probe with compatible fibered probe |
| Jerry (provisional) | 28 | 07/29/09 | JRY | NA | Fiber-bundle brain microscopic imaging procedure and apparatus |
| Microscopy in solid organs (provisional) | 29 | 09/17/09 | MSO | NA | Investigational procedure, optical probe and confocal microscopy system for solid organs |
| Jerry 2 (prov. JRY + new matter PCT) | 30 | 07/29/10 | JR2 | WO2011/013011 | Fiber-bundle brain microscopic imaging procedure and apparatus |
| Microscopy in Solid Organs 2 (prov. MSO + new matter PCT) | 31 | 09/17/10 | MS2 | WO2011/033390 | Investigational procedure, optical probe and confocal microscopy system for solid organs |
| Cellvizio with Photoactivation (CIP of CVZ2) | 32 | 01/10/11 | CVP | US 8,644,663 | Modular imaging system, modules for the system and procedure performed with the system |
| Continuous calibration (RICE) | 33 | 05/16/11 | RIC | WO2012156826 | Continuous, real-time calibration of fiber-optic microscopy images |
| Stabilized micropositioner | 34 | 06/29/11 | MPS | WO2013/000873 | Endoscopic instrument with supporting base |
| Mosaicing (Cont of MOS) | 35 | 07/08/11 | MOS_C | US 8,218,901 | Continuation of Mosaicing |
| Spiraler | 36 | 04/13/12 | SPI | WO2013/153448 | Miniaturized scanning system |
| Fluorescent markers | 37 | 05/18/12 | RED | WO2013/171583 | Red and far-red fluorescent dyes to characterize biological tissues at cellular level |
| Smart Review (provisional) | 38 | 10/11/13 | EVA | NA | Characterization method of images acquired with a medical video device |
| Smart Review 2 (prov. Smart Review + new matter PCT) | 39 | 05/23/14 | EV2 | WO2015052351 | Characterization method of images acquired with a medical video device |
| Smart Review (continuation) | 39 | 05/23/14 | EV3 | US 15/997,802 | Characterization method of images acquired with a medical video device |
| Smart Review (continuation) | 39 | 05/23/14 | EV4 | US 15/997,915 | Characterization method of images acquired with a medical video device |
| Smart Review (continuation) | 39 | 05/23/14 | EV5 | US 15/997,936 | Characterization method of images acquired with a medical video device |
| Jerry 3 (Div US) | 40 | 06/05/15 | JR3 | US2015-0265153 | Fiber-bundle brain microscopic imaging procedure and apparatus |

In general, the coverage of the Company's patents or patent applications accurately reflects the main aspects of the architecture of the technical solutions developed by the Company, namely:

- the system proper (photoexcitation, detection, scanning means, etc.);
- the endomicroscopic probes (optical probes + distal optics);
- image analysis and processing algorithms.

The Company also filed and continues to file patent applications aimed at protecting certain applications related to its products, such as:

- alveolar imaging;
- biliary duct imaging;
- solid organ imaging; and
- deep intra-cerebral imaging of animals.

#### 11.2.3 Territories protected

With a very limited number of exceptions, all of the Company's patent applications are systematically extended abroad through the PCT procedure. The minimum territories selected are still:

- the United States;
- Europe;
- Japan;
- Canada;
- Australia.

The most important patent applications have also been extended to China, India and Israel. In Europe, the countries selected for validation after issuance of the European patent are Germany, the United Kingdom, Spain and Italy.

#### 11.2.4 Litigation

The Company is not currently subject to any infringement proceedings brought by a third party. Likewise, to date the Company has not brought any such proceedings against a third party. However, the Company is doing its utmost to closely monitor the commercial activity of players in the field and the development of the patent landscape in order to fully ensure the freedom to use its products and guarantee that its rights are respected.

### 11.3 Collaboration, research, service and license agreements granted by or to the Company

Among the collaboration agreements currently in force, we cite the agreements relating to the PERSEE project, a collaborative project supported by OSEO in 2010 in the context of ISI (Industrial Strategic Innovation) projects.

PERSEE seeks to develop a robotic endomicroscopic solution, applied to the surgical treatment of digestive cancers. PERSEE has allied two industrial partners, Mauna Kea Technologies and Endocontrol, specializing in the development of robot-assisted surgical tools, an academic partner, the Institut des Systèmes Intelligent et de Robotique (ISIR) of the Université Pierre et Marie Curie, and two hospitals, the Institut de cancérologie Gustave Roussy and the Institut Mutualiste Montsouris.

The Consortium thus formed aims to develop, industrialize and market a device able to improve diagnosis and preoperative staging techniques for cancer patients.

The project is financed by BPI, and each party receives financing corresponding to its part of the research program. Furthermore, each party must individually bear the additional financing necessary to perform its part of the program.

Each party is responsible for its part of the research program and, vis-à-vis third parties, for its errors and omissions as well as those of its employees. The agreement provides that the parties mutually waive seeking damages for any indirect losses that they could come to cause one another mutually. In addition, the parties cannot conduct R&D work on a project the end result of which is the development of products or technologies competing with those that are the subject of the PERSEE project.

The agreement provides that the results of the project specific to each party remain its property. However, the joint results are the joint property of the parties having contributed to obtaining such results and must be the subject of rules of joint ownership.

In terms of commercial use, the agreement provides that the Company enjoys, during the entire term of the agreement and for a period of six months following its expiry or termination, an irrevocable option to license a non-exclusive right of use to the preexisting elements and the results of the other parties necessary for the industrial and commercial use of the project's results in its field of operations.

If a party wishes to withdraw from the project, for this it must obtain the consent of the steering committee and of OSEO, which may approve the proposal to withdraw, approve it under conditions, or refuse it. The agreement can also be terminated with respect to a party in the case of its failing to comply with its obligations, subject to the consent of OSEO. In this case, the defaulting party will lose all rights to the results arising from the performance of the agreement. Lastly, the agreement may be terminated in case the project's financing by OSEO is stopped, or by a unanimous decision of the parties.

The PERSEE project is structured into four successive phases, the last of which is expected to be completed in August 2018. In practice, the third of these phases was finished in July 2015, and the stage three end report was submitted to BPI France in May 2016. Following the end of this third phase in July 2015, BPI France and the partners embarked on the fourth phase, involving a multicenter clinical trial. After a technical validation provided by the third phase, this fourth phase should demonstrate the clinical benefit of a robotic endomicroscopy solution for cancer surgery. The fourth phase is currently in progress. Only at the end of this fourth phase will the PERSEE project be complete.

**License agreements granted by third parties**

As indicated above, the Company also holds two exclusive operating licenses for the entire world for technologies intended for *in vivo* and *in situ* microscopy, in humans and animals.

The first was granted by the Université Denis Diderot (or Paris 7) on November 22, 2000. It concerns *in vivo* microscopic tomography techniques of the human (or animal) retina still relatively far from an industrial and commercial application, which the Company therefore does not use yet. As of the registration date of this Universal Registration Document, the commercial and competitive consequences that the Company can expect from the future marketing of the products covered by the patents under license are difficult to quantify.

In the context of this license agreement, the Université Denis Diderot (Paris 7) granted the Company an exclusive operating license to some patents and patent applications, in all the countries covered by these patents, with the option to sub-license them.

Under this license, the Company undertook to pay, on top of an initial lump-sum fee, a proportional fee of 5% that will be calculated depending on the sale price of the products, which involves the payment of a "minimum" amount owed from the seventh year of the agreement.

This agreement is entered into for the term of validity of the last of the patents and may be terminated automatically in the case of full or partial transfer, court-ordered or voluntary liquidation, cessation of operations, or dissolution of the Company. Each party may furthermore terminate the agreement in case of non-performance of its obligations by the other party. The Université Denis Diderot (Paris 7) also has the option of terminating the agreement if the Company has not made any sales in a followed-up manner for a period of two consecutive years from the product's first release on the market.

The agreement provides for the option, for each party, to file patent applications on the improvements made to the licensed patents, subject to having communicated said improvements to the other party.

The license is granted with the sole guarantee of the material existence of the patents. In case of an action for infringement lodged against the Company at the time of the manufacture or operation of the products, no indemnification may be claimed from the Université Denis Diderot (Paris 7).

The second was granted by the INSERM-APHP on January 2, 2001. It concerns a fiber optic endomicroscopic technology complementary to the Cellvizio.

In the context of this license agreement, the INSERM-APHP granted the Company an exclusive, worldwide operating license to a technology protected in part by patents and know-how.

Under this license, the Company undertook to pay a fee calculated on the net sales of the products marketed by the Group. The calculation basis for this fee is 0.25% of the proceeds from the sale of these systems. The Company additionally undertook to contribute the financing necessary for the development work and to cover the costs of filing patents and maintaining them in force.

The agreement will remain in force until the later of: the expiration date of the most recent patent, or at the end of ten years from when the product is first marketed if said product is not protected under a patent in the country where it is marketed.

The Company does not believe the loss of these exclusive licenses would have a material negative impact on its business.

## 11.4 Other elements of intellectual property

The Company holds the “Cellvizio®” trademark in numerous countries and regions, in particular France, Europe, Australia, Japan, the United States of America, China, India, Israel and Canada.

It also holds in France the trademarks “MKT”, “Mauna Kea Technologies”, “Proflex” and “Confocal Miniprobe”.

The Company is the owner of more than 70 domain names including: “cellvizio.fr”, “diagnosingbarretts.com”, “maunakeatech.fr”, “cellvizio.com”, “maunakeatech.com”, etc.

# SECTION 12
# 12. TRENDS

## 12.1 Principal trends since the end of the last financial year

First quarter 2020 sales.

Shipments of Cellvizio® systems fell to 8 units in the first quarter of 2020, versus 13 units a year earlier. Total system deliveries include one sale and 2 placements in the United States in the first quarter of 2020, compared to no sales and 7 placements a year earlier. Deliveries of consumable probes dropped 45% year-on-year to 107 in the first quarter of 2020, versus 195 deliveries a year earlier, mainly due to the slowdown in procedures related to the COVID-19 pandemic.

Total sales for the first quarter of 2020 period were €1.5 million, down 14% year-over-year. First quarter 2020 sales performance was driven primarily by a 27% decrease in consumables sales and, to a lesser extent, a 1% decrease in system sales in the period. The year-over-year decrease in total consumables sales in the first quarter of 2020 was a result of lower procedure-related demand for Cellvizio probes in the Company's targeted commercial geographies around the world as a result of the COVID-19 pandemic. First quarter 2020 total sales performance benefitted from stronger-than-expected demand for Cellvizio systems in both the U.S. and APAC during the period.

## 12.2 Known trend, uncertainty, request for commitment, or event reasonably likely to influence Company outlook

N/A.

# SECTION 13
# 13. PROFIT PROJECTIONS OR ESTIMATES

The Company does not intend to make any profit projections or estimates.

# SECTION 14
# 14. ADMINISTRATIVE, EXECUTIVE AND SUPERVISORY BODIES AND GENERAL MANAGEMENT

## 14.1 Executives and directors

### 14.1.1 Members of the Board of Directors

The Board is composed of at least three members, two of whom, wherever possible, must be independent members within the meaning of the corporate governance code published in September 2016 by MiddleNext and approved as a model code by the Autorité des Marchés Financiers (the "MiddleNext Code").

At the date of this Universal Registration Document, the Company's Board of Directors is composed of seven Directors. No non-voting Board members were appointed on this day.

| Name or company name | Role | Date of appointment | Expiration of term of office | Committee |
|---|---|---|---|---|
| Alexandre Loiseau | Chairman of the Board of Directors | Appointed as Director by the OGM of May 3, 2017<br><br>Reappointed by the AGM of July 2, 2020<br><br>Appointed Chairman of the Board of Directors on October 10, 2018 with effect from October 22, 2018 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | Member and Chairman of the Strategic Committee - Member of the Compensation Committee |
| Chris McFadden | Independent director | Appointed as Director by the OGM of May 3, 2017<br><br>Reappointed by the AGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | Member and Chairman of the Compensation Committee |
| Joseph DeVivo | Independent director | Appointed as Director by the OGM of May 3, 2017<br><br>Reappointed by the AGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | Member of the Audit and Strategic Committees |
| Jennifer F. Tseng | Independent director | Appointed as Director by the OGM of May 3, 2017<br><br>Reappointed by the AGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | Member of the Compensation Committee |
| Molly O'Neill | Independent director | Appointed as Director by the OGM of May 30, 2018<br><br>Reappointed by the AGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | Member and Chairman of the Audit Committee |
| Robert Gershon | Director | Coopted by the Board of Directors of October 10, 2018 with effect from October 22, 2018 - Ratified by the OGM of December 19, 2018<br><br>Reappointed by the AGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | N/A |
| Claire Biot | Director | Appointed as Director by the OGM of July 2, 2020 | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2021 | N/A |

On October 10, 2018 the Board of Directors appointed, with effect from October 22, 2018:

- Mr. Alexandre Loiseau as Chairman of the Board of Directors and Chairman of the Strategic Committee;
- Mr. Christopher McFadden as member of the Board of Directors and Chairman of the Compensation and Appointments Committee;
- Mr. Robert L. Gershon as CEO and member of the Board of Directors;
- Mr. Christophe Lamboeuf as Deputy CEO while maintaining his role as Chief Financial Officer; and

- Ms. Molly O'Neill as Chairwoman of the Audit Committee.

Independence of Board members

Board members are considered independent if they have no financial, contractual, family or other significant close relationship with the Group or its management that is likely to influence their judgment.

The independence of the Board members must be verified by the Board in accordance with the following criteria set out by the Middlenext Code:

- is not, and has not over the past five years been, an employee or executive officer of the Company or of any company in its group;
- is not, and has not over the past two years been, in a significant relationship with the Company or its group (as a client, supplier, competitor, service provider, creditor, banker, etc.);
- is not a reference shareholder of the Company and does not hold a significant portion of its voting rights;
- does not have a close relationship or family ties with a corporate officer or reference shareholder; and
- has not, over the past six years, been a statutory auditor of the Company.

If possible, at least one of the independent members must also have special expertise in financial or accounting matters so as to be appointed to the Audit Committee.

Every year, the Board of Directors will assess, on a case-by-case basis, the status of each member vis-a-vis the aforementioned criteria.

At its meeting of April 27, 2020, the Board of Directors deemed that four of its members, namely Messrs. Christopher McFadden and Joseph DeVivo, and Mses. Jennifer F. Tseng and Molly O'Neill, satisfied the independence criteria defined by the Middlenext Code.

Terms of office

In accordance with the thirty-fourth resolution adopted by the Combined General Meeting of July 2, 2020, the Director's term of office has been reduced to two years, versus three years previously. This term is tailored to the specific requirements of the Company.

Exceptionally and exclusively to enable the staggered terms of office of the Directors to be implemented or maintained, the Ordinary General Meeting may appoint one or more Directors for a term of one or three years.

Ethics

The internal rules and code of ethics were approved by the Board of Directors. These documents outline the rules which must be followed by the members of the Board, in accordance with recommendation No. 1 of the MiddleNext Code.

Director selection

At the time of appointment or renewal of the term of office of each director, details of their experience, expertise and list of appointments held is set out in the Universal Registration Document and shared at the Annual General Meeting. This information is available online on the Company's website, as suggested in the MiddleNext Code, under recommendation No. 8. The appointment and/or renewal of each director shall be the subject of a specific resolution submitted to the shareholders' vote.

The applicable rules are statutory and are in accordance with the law.

**Preparation and Organization of tasks undertaken by the Board**

The Company's Board of Directors has a set of internal rules, in accordance with recommendation No. 7 of the MiddleNext Code. This document, approved by the Board of Directors at its meeting of May 25, 2011 and amended by the Board of Directors at its meeting of March 21, 2017, is available on the Company's website.

In compliance with recommendation No. 2, these internal rules, in the clause entitled "Disclosure of interest" on the prevention of conflicts of interest, state that a director who finds him or herself in a situation of conflict of interest, is obliged to inform the members of the Board as such and to determine whether he/she should abstain from voting and/or taking part in Board discussions.

In compliance with recommendation No. 4 of the MiddleNext Code, outside of Board meetings and when in the interest of the Company, the directors must regularly be provided with all important information relating to the Company, that is likely to have an impact on the commitments and financial position thereof. They may ask for any further explanations or additional information, and more generally, may request access to any information they deem useful.

To take an effective part in the Board's work and deliberations, each member of the Board is provided with whatever additional documents he or she thinks useful. Such requests are made to the Chairman or, when appropriate, to any senior executive of the Company (Chief Executive Officer or Chief Operating Officer).

Each member of the Board is authorized to meet with the Company's senior executives, so long as he or she first informs the Chairman of the Board and the Chief Executive Officer.

The Board is regularly informed by the Chief Executive Officer of the Company's and the Group's financial position, cash position, financial commitments and significant events.

Finally, any new member of the Board may ask to receive training in particular aspects of the Company or Group, their lines of business and their business segments.

The members of the Board are convened by letter, fax or email at least five (5) days before each meeting.

The Board may also be convened by any other means, even verbally, if all the Board members in office are present or represented at the meeting.

All documents or drafts of documents that could be informative to the members about the meeting agenda and any matters brought before the Board are sent, handed or made available to the members of the Board within a reasonable time before the meeting.

Moreover, whenever it meets, the Board is informed about the Company's financial position, cash position and commitments.

In accordance with Recommendation 11 of the MiddleNext Code, once a year the Board discusses the way it functions and, at least once every three years, undertakes a formal assessment, where appropriate with an outside consultant.

The purpose of this assessment, moreover, is to make sure that the important questions are suitably prepared and debated, and to measure the contribution of each member to the Board's work, chiefly in regard to his or her qualifications and degree of involvement.

**Report on the Board's activities during the 2019 financial year**

The minutes of each meeting are prepared by the Chief Executive Officer, then approved by the Chairman, who submits them for approval at the next meeting. They are copied into the minutes register following signature by the Chairman and one Director.

During the 2019 financial year, the Board of Directors met seven times on February 7, March 19, May 19, July 25, September 19, November 20 and December 13. All meetings were chaired by the Chairman of the Board. The directors' attendance rate was close to 97%.

As set out in recommendation No. 14 of the MiddleNext Code, the majority of issues are addressed at the meetings of the Board. Nevertheless, the issues relating to the assumption of an accident and the sudden unavailability of the director were not addressed during 2019 and will be added to the agenda of the next Board meeting.

Prior to Board meetings, the directors are sent all documents required to enable them to prepare for the issues to be discussed.

Lastly, in accordance with recommendation No. 12 of the MiddleNext Code, executives must offer minority shareholders the opportunity to meet with them and discuss the operation of the Company. Such was the case at the Annual General Meeting of July 5, 2019 in Paris.

In accordance with recommendation No. 1 of the MiddleNext Code, the executive directors do not hold more than two other appointments as directors in listed companies outside the Board's group.

The CEO uses the Company's registered office as his professional address.

The professional addresses of the other directors are as follows:

- Mr. Alexandre Loiseau is domiciled at Mauna Kea Technologies;
- Mr. Robert L. Gershon is domiciled at Mauna Kea Technologies;
- Mr. Christopher McFadden is domiciled at Kohlberg Kravis Roberts 555 California Street, 50th Floor, San Francisco, CA 94104, United States;
- Mr. Joseph DeVivo is domiciled at InTouch Health, 7402 Hollister Ave., Goleta, CA 93117, United States;
- Ms. Jennifer F. Tseng is domiciled at Boston Medical Center, 88 East Newton Street, C-500, Boston, MA 02118, United States;
- Ms. Molly O'Neill is domiciled at Proteus Digital, 2600 Bridge Pkwy, Ste. 101, Redwood City, CA 94065, United States;

- Ms. Claire Biot is domiciled at Dassault Systems, 10 rue Marcel Dassault, CS 40501, 78946 Vélizy-Villacoublay, France.

The management expertise and experience of these persons come from the various employee and management positions that they previously held (see Section 14.1.3

There are no ties of blood or marriage between the persons listed above.

Over the past five years, none of these persons has:

been convicted of fraud;
been associated in their capacity as executive or director with a bankruptcy, sequestration or liquidation;
been prohibited from acting in a managerial capacity; or
been subject to incriminations or official public sanctions pronounced by legal or regulatory authorities.

Balanced gender representation

The Board includes three women out of seven members at the date of this report. The Company is in compliance with the law of January 27, 2011 on balanced gender representation on boards of directors, the Board of Directors being comprised of less than eight members, therefore the difference between the number of directors of each sex shall not be greater than two.

### 14.1.2 Other corporate positions as of December 31, 2019

| Name and roles held within the Company | Main roles held in all companies | Other appointments held in all companies |
|---|---|---|
| Alexandre Loiseau, Chairman of the Board of Directors | Therapixel SA, Chairman of the Board of Directors | MDoloris SA, member of the Strategic Committee |
| Christopher McFadden, independent director, Chairman of the Board of Directors through October 22, 2018 | Kohlberg Kravis Roberts, Managing Director | - Foundation Radiology Group, independent director<br>- InnovaTel Telepsychiatry, Director<br>- Reliant Rehabilitation, Board of Directors observer<br>- Athena Health, Board of Directors observer<br>- Healthcare Staffing Services, Board of Directors observer |
| Joseph DeVivo - independent director | InTouch Health, Chief Executive Officer | - ALSAC/St. Jude, Director<br>- AdvaMed, Director |
| Jennifer F. Tseng – independent director | Boston University School of Medicine, Chief and Chair of the Surgery Department | N/A |
| Molly O'Neill – independent director | St George's University, Director of growth and strategy | - Qure Medical, Director<br>- Rocky Vista University Boards, Director |

### 14.1.3 Director biographies

**Alexandre (Sacha) Loiseau, Ph D.**
Chairman of the Board of Directors
Chairman of the Strategic Committee

Sacha Loiseau founded Mauna Kea Technologies in May 2000 and was its CEO for 18 years.

Co-inventor of the Cellvizio confocal laser endomicroscopy platform, he oversaw and raised more than €120 million to finance the development of Mauna Kea since its creation, taking the Company public on the Euronext stock market in July 2011.
In 2013, Sacha was appointed co-leader of the Industrial Plan on Medical Devices and New Health Care Equipment, then a member of the "Medicine of the Future" steering committee.
Sacha helped found MedTech, the French association of business leaders in innovative medical technologies in France, and has served as its Vice President since June 2016.
Sacha started his career at the National Center for Space Studies (CNES) in Toulouse and at the Paris Observatory, then joined NASA's Jet Propulsion Laboratory (JPL) in Pasadena, California, as a research scientist.

He is a graduate of the École Polytechnique in Paris and has a Ph.D. in Astrophysics and Space Instrumentation from the Université Paris-Diderot. He has authored many scientific articles, is cited as an inventor on seven patents and was a 2018 Marius Lavet award winner.

**Robert L. Gershon**
Chief Executive Officer
Member of the Board of Directors

Robert L. Gershon has more than 30 years of experience in the field of medical technologies.

Robert is a seasoned executive with more than 30 years of experience in managing business strategies and general management at medical technology companies.
Robert was Chief Executive Officer of Bovie Medical (NYSE: BVX) from December 2013 to December 2017, where he successfully led the marketing of new technologies, repositioned the Company's product portfolio and improved its financial profile. Previously, he held management positions at Henry Schein Inc. and Covidien (now Medtronic).
Rob has an MBA from J.L. Kellogg Graduate School of Management of Northwestern University and a BSBA from American University in Washington, D.C.

**Christopher D. McFadden**
Member of the Board of Directors
Chairman of the Compensation and Appointments Committee

Christopher McFadden is the Senior Managing Director at Kohlberg Kravis Roberts (KKR), a global investment fund.

Prior to joining KKR, Mr. McFadden founded Canyon Healthcare Partners, a healthcare private equity firm and was a Senior Advisor to Athyrium Capital Management.
Previously, he was a Managing Partner at Health Evolution Partners and a Senior Financial Analyst at Goldman Sachs & Co. in New York, where he was a member of the Goldman Sachs' Americas Special Situations Group (AmSSG) focused on healthcare private investing.
Mr. McFadden is Chairman of InnovaTel Telepsychiatry and a member of the Board of Directors at ValueCentric.

**Joseph DeVivo**
Member of the Board of Directors

Joseph DeVivo is Chief Executive Officer of InTouch Health, Inc.

Previously, Mr. DeVivo was CEO and member of the Board of Directors of AngioDynamics, Global Chairman of Smith & Nephew Orthopedics, CEO and member of the Board of Directors of RITA Medical Systems, Chief Operating Officer and member of the Board of Directors of Computer Motion Incorporation (CMI), Vice President and Chief Executive Officer of U.S. Surgical/Davis, a division of Tyco International Healthcare representing $350 million.
Mr. DeVivo received his B.S. in Business Administration from the E. Claiborne Robins School of Business at the University of Richmond.

**Jennifer F. Tseng**
Member of the Board of Directors

Jennifer F. Tseng is Head and Chairwoman of Surgery at Boston University School of Medicine.

Dr. Tseng is a renowned oncologist and gastro-enterological surgeon whose practice focuses on the upper gastrointestinal tract. She has led research groups at Beth Israel Deaconess Medical Center in the fields of oncology, gastroenterology, endocrine and breast problems, as well as melanomas, sarcomas, and other malignant tumors.
Dr. Tseng is a graduate of Stanford and obtained a medical doctorate from the University of California in San Francisco as well as a Master's in Public Health from the Harvard T.H. Chan School of Public Health. She interned in General Surgery at Massachusetts General Hospital then conducted research in molecular medicine at Harvard Medical School/Children's Hospital of Boston and in surgical oncology at the University of Texas MD Anderson Cancer Center in Houston.

**Molly O'Neill**
Member of the Board of Directors
Chairman of the Audit Committee

Molly O'Neill, Chief Growth and Strategy Officer of St. George's University, Grenada.

Over the past 30 years Ms. O'Neill has held senior leadership roles at Tenet Healthcare Corporation, Ascension Health Care Network, Duke Medicine and Partners Healthcare in Boston. From 2015 to 2017 she was Chief Commercial Officer of Proteus Digital Health.
Earlier in her career she worked at Gambro Healthcare as Vice President of Disease Management & Business Development. During her career she has demonstrated an exceptional ability to bring clinical value to patients and all stakeholders in the healthcare sector.
Molly received her B.Sc. in Journalism and her M.S. in Health Care Administration from Virginia Commonwealth University/Medical College of Virginia.

**Claire Biot**
Member of the Board of Directors

Claire Biot is Vice President, Life Sciences Industry at Dassault Systèmes.

Claire Biot is a graduate of the Ecole Polytechnique and obtained a doctorate in immuno-oncology at the Pasteur Institute. Claire then became Division Head, Pricing and Reimbursement of Health Products at the Ministry of Health, before becoming Chief Executive Officer of AGEPS, AP-HP's General Agency for Health Equipment and Products, with several assignments including health products and technologies purchasing for the group's 39 hospitals (annual budget of €1.6 billion). After 3 years at AGEPS, she joined Dassault Systèmes as Vice President, Life Sciences Industry, tasked with developing Dassault Systèmes' market share and sales in the life sciences and healthcare sector.

## 14.2 Conflicts of interest within the administrative and management bodies and General Management

The Chairman, Chief Executive Officer and certain directors, who comprise the management team, are shareholders, directly or indirectly, of the Company and/or holders of financial instruments granting access to the Company's share capital. See Section 17.2 for 17.2

As of the date of this Universal Registration Document, there were no related party agreements.

To the knowledge of the Company, there exists no current or potential conflict of interest between the duties with regard to the Company and the private interests and/or other duties of persons comprising the administrative and executive bodies and General Management, as described in Section 14.1above.

# SECTION 15
# 15. COMPENSATION AND BENEFITS

## 15.1 Compensation policy of corporate officers

The "Sapin 2" law of December 9, 2016 introduced a new system for voting at shareholders' meetings on the compensation of executive corporate officers of companies whose shares are admitted to trading on the regulated market of Euronext Paris.

This system was modified in particular by the "Pacte" law no. 2019-486 on May 22, 2019 as well as by ordinance no. 2019-1234 of November 27, 2019 and by decree no. 2019-1235 of November 27, 2019.

They provide for two types of vote:

- a first *ex ante* vote of the Ordinary General Meeting of Shareholders related to the compensation policy of the Chairman of the Board of Directors, the Chief Executive Officer and the members of the Board of Directors of Mauna Kea, due to their corporate offices (Article L. 225-37-2 of the French Commercial Code). The compensation policy for corporate officers describes all components of their fixed and variable compensation, and explains the decision-making process followed for its determination, review and implementation. This *ex ante* vote on the compensation policy applicable to each of the Company's corporate officers will be submitted to vote annually;
- a second *ex post* vote of the Ordinary General Meeting of Shareholders on (i) a draft resolution related to the information mentioned in Article L. 225-37-3 (I) of the French Commercial Code (information on corporate officer compensation as a whole with respect to the past financial year), and (ii) distinct draft resolutions for each corporate officer concerned, on the fixed, variable and exceptional elements comprising the total compensation and benefits in kind paid to each of them during the past financial year or granted with respect to the same financial year (Article L. 225-100 of the French Commercial Code).

### 15.1.1 Executive compensation

The Company applies all of the recommendations of the MiddleNext Code on executive and non-executive pay.

For the 2019 financial year, the variable compensation targets for the Chief Executive Officer were set and approved by the Board of Directors on the recommendation of the Compensation Committee on March 19, 2019. These objectives took into account the Company's sales growth.

At its meeting on March 24, 2020, the Board of Directors, acting on the proposal from the Compensation Committee, examined the level of achievement of these targets and decided to pay the Chief Executive Officer the variable compensation corresponding to those targets, subject to the Company's performance.

Executive corporate officers do not receive directors' fees in respect of their corporate office within the Company. In addition, they are not entitled to any deferred compensation, retirement benefits or pension plans, in accordance with recommendation Nos. 16 and 17 of the MiddleNext Code.

Within the framework of its executive and employee compensation and incentive policy, the Company awarded bonus preferred shares to Company employees and stock options to employees of its subsidiary, respectively, in September and November 2019 and in February, May, July and November 2019.

**Restrictions imposed by the Board in respect of the exercise of options granted or sale of bonus shares granted to executives.**

In accordance with the provisions of Article L. 225-197-1 of the French Commercial Code, the Chief Executive Officer must hold in registered form, until the termination of his duties, 10% of the shares awarded by the Board of Directors, within the limit of a number of shares whose cumulative value does not exceed one year of total gross compensation.

**Approval of the elements of compensation due or granted to the Chairman, the Chief Executive Officer and the Deputy CEO for the 2019 financial year**

In accordance with Article L. 225-100-II of the French Commercial Code, the fixed, variable and exceptional elements of compensation granted or still to be granted for the 2019 financial year to the Chairman, Chief Executive Officer and Deputy CEO by virtue of their offices, as approved by the Board of Directors in line with the principles and criteria approved by the General Meeting on December 19, 2018 under its second and fourth resolutions and set out in the "Compensation of corporate officers" section above, were approved by shareholders at the General Meeting called to approve the financial statements for the 2019 financial year.

**Principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind due to the Chairman, the Chief Executive Officer and the Deputy CEO for 2020.**

Pursuant to Article L. 225-37-2 of the French Commercial Code, the Board of Directors submits to the approval of the General Meeting the principles and criteria applicable to the determination, distribution and allocation of variable, and exceptional elements of the total compensation and benefits in kind attributable to the President, Chief Executive Officer and Deputy CEO resulting from the performance of their term of office for the 2020 financial year and constituting the compensation policy relating to them.

These principles and criteria, adopted by the Board of Directors on the recommendation of the compensation Committee, are set out below:

**For Mr. Alexandre Loiseau, Chairman of the Board of Directors:**

| Compensation elements | Principles | Criteria for determination |
|---|---|---|
| Fixed compensation | The Chairman receives a fixed compensation payable in 12 monthly installments | The gross annual amount of this compensation, which takes into account the additional significant tasks entrusted by the Board of Directors to its new Chairman, was set at €236,740, less the directors' fees paid to him during the same period. |
| Directors' fees | The Chairman receives directors' fees | As for every Director, the Chairman may receive directors' fees, the amount of which is decided by the Board, within the limit of the budget approved by the General Meeting) and the principles adopted by the Board of Directors. The Board, based on its his attendance and the time devoted to his office, including, where applicable, within the committee or committees set up by the Board. |
| Benefits in kind | Provision of a vehicle<br>Corporate officer unemployment insurance (GSC) | |

In addition, the Chairman may be granted the option to subscribe, for valuable consideration, to share warrants subject to presence conditions.

**For Mr. Robert L. Gershon, Chief Executive Officer:**

| Compensation elements | Principles | Criteria for determination |
|---|---|---|
| Fixed compensation | The CEO receives a fixed compensation payable in 12 monthly installments | This fixed compensation has been determined by the Board of Directors on the recommendation of the Compensation Committee. |
| Variable compensation | The Chief Executive Officer receives a variable compensation up to 100% of his fixed compensation, if 100% of the objectives have been attained. | This variable compensation is based half on Company objectives and half on objectives set by the Board of Directors on the recommendation of the Compensation Committee.<br>These objectives are not made public for reasons of confidentiality. |

In addition, the CEO may be granted share subscription options and bonus shares, subject to conditions of attendance and performance.

Finally, Robert L. Gershon may claim a severance compensation under the following conditions:

In addition, the CEO may be granted stock options, subject to conditions of attendance and performance.

Finally, Robert L. Gershon may claim a severance compensation under the following conditions:

In the event of dismissal not caused by gross or serious misconduct or resignation caused by a significant reduction of its awards or compensation, or following a change of control of the Company, Robert L. Gershon would receive, provided that he has attained the objectives on which his normal bonus is based (up to 100% of his fixed compensation) by more than 50%, (i) a monthly indemnity

equal to his salary for 12 months following his departure, (ii) the pro rata of his annual bonus until the date of his departure (calculated by reference to the level of achievement of the Company's objectives for the last fully completed financial year, if the departure is during the first half-year, or the current financial year if during the second half-year, and (iii) an amount equivalent to the cost of maintaining his medical insurance for 12 months. The schedule for exercising his options would continue in this case for 12 months following his departure as if he had not left the Company.

Granting this severance compensation was authorized by the Board of Directors meeting on October 10, 2018, in accordance with the provisions of Article L. 225-38 of the French Commercial Code.

It is recalled, to the extent necessary, that no payment of any kind whatsoever may be made before the Board of Directors acknowledges, on or after termination of his duties, compliance with the above conditions.

**For Mr. Christophe Lamboeuf, Deputy CEO:**

It is recalled that all of the compensation received by Mr. Christophe Lamboeuf is for his salaried CFO duties:

| Compensation elements | Principles | Criteria for determination |
|---|---|---|
| Fixed compensation | The CEO receives a fixed compensation for his salaried CFO duties payable in 12 monthly installments | This fixed compensation has been determined by the Board of Directors on the recommendation of the Compensation Committee. |
| Variable compensation | The Deputy CEO receives a variable compensation up to 55% of his fixed compensation, if 100% of the objectives have been attained. | This variable compensation is based 30% on Company objectives, and 25% on objectives set by the Board of Directors on the recommendation of the Compensation Committee.<br>These objectives are not made public for reasons of confidentiality. |
| Benefits in kind | Provision of a vehicle | |

In addition, the Deputy CEO may be granted share subscription options and/or bonus shares, subject to conditions of attendance and performance.

In accordance with Article L. 225-100 of the French Commercial Code, the amounts resulting from the implementation of these principles and criteria will be submitted for shareholder approval at the General Meeting called to approve the financial statements for the 2019 financial year.

| **Summary table of compensation and options and shares granted to each executive corporate officer** | | |
|---|---|---|
| **Alexandre Loiseau**<br>(Chairman of the Board of Directors as of October 22, 2018) | Financial year ended on 12/31/2019 (in euros) | Financial year ended on 12/31/2018 (in euros) |
| Compensation due for the period (detailed in Table 2) | 251,845 | 48,441 |
| Valuation of options granted during the period | N/A | N/A |
| Valuation of performance shares granted during the period | N/A | N/A |
| **Alexandre Loiseau**<br>(Chief Executive Officer until October 22, 2018) | Financial year ended on 12/31/2019 (in euros) | Financial year ended on 12/31/2018 (in euros) |
| Compensation due for the period (detailed in Table 2) | N/A | 217,804 |
| Valuation of options granted during the period | N/A | N/A |

| | | |
|---|---|---|
| Valuation of performance shares granted during the period | N/A | 373,050 |
| **Robert L. Gershon** (Chief Executive Officer) - as of October 22, 2018 | Financial year ended on 12/31/2019 (in euros) | Financial year ended on 12/31/2018 (in euros) |
| Compensation due for the period (detailed in Table 2) | 532,350 | 82,450 |
| Valuation of options granted during the period | N/A | 481,286 |
| Valuation of performance shares granted during the period | N/A | N/A |
| **Christophe Lamboeuf** (Deputy CEO) - as of October 22, 2018 | Financial year ended on 12/31/2019 (in euros) | Financial year ended on 12/31/2018 (in euros) |
| Compensation due for the period (detailed in Table 2) | 239,821 | 128,019 |
| Valuation of options granted during the period | N/A | 99,480 |
| Valuation of performance shares granted during the period | N/A | N/A |

**Summary of compensation for each executive corporate officer**

| **Alexandre Loiseau** (Chairman of the Board of Directors) | Amounts due for the year ended 12/31/2019 (in euros) | | Amounts due for the year ended 12/31/2018 (in euros) | |
|---|---|---|---|---|
| | Amounts due | Amounts paid | Amounts due | Amounts paid |
| - fixed compensation | 163,740 | 163,740 | 31,692 | 31,692 |
| - variable compensation | 0 | 0 | 0 | 0 |
| - exceptional compensation | 0 | 0 | 0 | 0 |
| - directors' fees | 73,000 | 68,950 | 14,200 | 0 |
| - benefits in kind | 15,105 | 15,105 | 2,550 | 2,550 |
| TOTAL | 251,845 | 247,795 | 48,441 | 34,241 |
| **Alexandre Loiseau** (Chief Executive Officer) | Amounts due for the year ended 12/31/2019 (in euros) | | Amounts due for the year ended 12/31/2018 (in euros) | |
| | Amounts due | Amounts paid | Amounts due | Amounts paid |
| - fixed compensation | 0 | 0 | 165,575 | 165,575 |
| - variable compensation | 0 | 39,899[(1)] | 39,899[(1)] | 36,900 |
| - exceptional compensation | 0 | 0 | 0 | 0 |
| - directors' fees | 0 | 0 | 0 | 0 |
| - benefits in kind | 0 | 0 | 12,330 | 12,330 |

| | | | | |
|---|---|---|---|---|
| TOTAL | 0 | 39,899 | 217,804 | 214,805 |
| **Robert L. Gershon** (Chief Executive Officer) | Amounts due for the year ended 12/31/2019 (in euros) | | Amounts due for the year ended 12/31/2018 (in euros) | |
| | Amounts due | Amounts paid | Amounts due | Amounts paid |
| - fixed compensation | 352,805 | 352,805 | 65,979 | 65,979 |
| - variable compensation | 179,545[2] | 16,471[1] | 16,471[1] | 0 |
| - exceptional compensation | 0 | 0 | 0 | 0 |
| - directors' fees | 0 | 0 | 0 | 0 |
| - benefits in kind | | | 0 | 0 |
| TOTAL | 532,350 | 369,276 | 82,450 | 65,979 |
| **Christophe Lamboeuf** (Deputy CEO) | Amounts due for the year ended 12/31/2019 (in euros) | | Amounts due for the year ended 12/31/2018 (in euros) | |
| | Amounts due | Amounts paid | Amounts due | Amounts paid |
| - fixed compensation | 185,000 | 185,000 | 111,923 | 111,923 |
| - variable compensation | 53,928[2] | 16,096[1] | 16,096[1] | 0 |
| - exceptional compensation | 0 | 0 | 0 | 0 |
| - directors' fees | 0 | 0 | 0 | 0 |
| - benefits in kind | 893 | 893 | 0 | 0 |
| TOTAL | 239,821 | 201,989 | 128,019 | 111,923 |

[1] Variable compensation with respect to financial year 2018 paid in 2019
[2] Variable compensation with respect to financial year 2019 which will be paid in 2020

| **Stock options granted during the financial year to each executive corporate officer by the issuer and by each Group company** | | | | | | |
|---|---|---|---|---|---|---|
| Name of the executive corporate officer | Plan No. and date | Type of options (purchase or subscription) | Valuation of the options according to the method used for the consolidated financial statements | Number of options granted during the financial year | Exercise price | Exercise period |
| N/A | | | | | | |

| **Stock options exercised during the financial year by each executive corporate officer** | | | | |
|---|---|---|---|---|
| Name of the executive corporate officer | Plan No. and date | Number of options exercised during the period | Exercise price | Year of grant |
| N/A | | | | |

| **Bonus shares granted to each executive corporate officer** | | | | | | |
|---|---|---|---|---|---|---|
| Performance shares granted during the | Plan No. and date | Number of shares | Valuation of the options | Acquisition date | Vesting date | Performance conditions |

| | | | | | | |
|---|---|---|---|---|---|---|
| period by the issuer and by each Group company | | granted during the period | according to the method used for the consolidated financial statements | | | |
| N/A | | | | | | |

| **Bonus shares vesting during the period for each executive corporate officer** | | | | |
|---|---|---|---|---|
| Performance shares vesting for each executive officer | Plan No. and date | Number of shares vesting during the period | Vesting condition | Year of grant |
| N/A | | | | |

The following table contains details of the conditions of compensation and other benefits granted to executive officers:

| Executive corporate officers | Employment contract | | Supplementary pension plan | | Compensation or benefits due or likely to be due owing to termination or change of role | | Compensation for non-compete clause | |
|---|---|---|---|---|---|---|---|---|
| Date on which term of office expired: | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019 | | | | | | | |
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Robert L. Gerson, Chief Executive Officer | | X | | X | | X | | X |
| Date on which term of office began: | October 22, 2018 | | | | | | | |
| Date on which term of office expired: | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019 | | | | | | | |

| Executive corporate officers | Employment contract | | Supplementary pension plan | | Compensation or benefits due or likely to be due owing to termination or change of role | | Compensation for non-compete clause | |
|---|---|---|---|---|---|---|---|---|
| Date on which term of office expired: | At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019 | | | | | | | |
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Christophe Lamboeuf Deputy CEO | X | | | X | | X | | X |
| Date on which term of office began: | October 22, 2018 | | | | | | | |
| Date on which term of office expired: | N/A | | | | | | | |

### 15.1.2 Directors' fees and other compensation received by non-executive corporate officers

| **Table of directors' fees and other compensation received by non-executive corporate officers** | | | | |
|---|---|---|---|---|
| Members of the Board of Directors | Directors' fees paid for the year ended 12/31/2019 (in euros) | Directors' fees paid for the year ended 12/31/2018 (in euros) | Plans awarded in 2019 | Plans awarded in 2018 |
| Christopher McFadden | | | | |
| - directors' fees | 49,831 | 74,581 | | |

| | | | | |
|---|---|---|---|---|
| - other compensation | - | - | | |
| - value of BSA granted (1) | | | 8,500 | 11,200 |
| TOTAL | 49,831 | 74,581 | 8,500 | 11,200 |
| Joseph DeVivo | | | | |
| - directors' fees | 46,278 | 42,778 | | |
| - other compensation | - | - | | |
| - value of BSA granted (1) | | | 6,800 | - |
| TOTAL | 46,278 | 42,778 | 6,800 | |
| Molly O'Neill | | | | |
| - directors' fees | 33,806 | 33,556 | | |
| - other compensation | - | - | | |
| - value of BSA granted (1) | | | 6,800 | 7,500 |
| TOTAL | 33,806 | 33,556 | 6,800 | 7,500 |
| Jennifer F. Tseng | | | | |
| - directors' fees | 38,084 | 35,584 | | |
| - other compensation | - | - | | |
| - value of BSA granted (1) | | | 6,800 | 9,000 |
| TOTAL | 38,084 | 35,584 | 6,800 | 9,000 |

(1) €0.30 per share warrant in February 2018, €0.28 per share warrant in November 2018 and €0.17 in May 2019

The Board of Directors meeting of May 25, 2016 set the principles for distributing directors' fees between its members as follows:

- the Board of Directors allocates directors' fees on a yearly basis and pays them on a quarterly basis;
- the Chairman of the Board of Directors is allocated €55,000 per year, prorata temporis;
- the independent directors, with the exception of the Chairman of the Board of Directors, are each allocated €30,000 pro rated to their attendance rate at Board meetings;
- the Chairmen of the Audit and Compensation Committees are each allocated €10,000 per year for this role;
- the members of the Audit Committee, the Strategic Committee and Compensation Committee other than the Chairmen are allocated €8,000 for this role.

Directors receive no special pension, termination benefit or non-compete compensation.

It is recalled that the General Meeting of May 3, 2017 set the budget for directors' fees at €245,000 for the 2017 financial year as well as for each subsequent financial year, until otherwise decided by the Ordinary General Meeting.

With effect from the financial year beginning January 1, 2020, the overall annual amount referred to in Article L. 225-45 of the French Commercial Code to be allocated to the members of the Board of Directors as compensation for their work was set at €285,000 by the Combined General Meeting of July 2, 2020.

The information contained in the following table on historical stock options granted to corporate officers presents, as of the filing date of this Universal Registration Document, all stock options issued by the Company to its corporate officers and employees:

| HISTORICAL STOCK OPTION GRANTS | | | | | |
|---|---|---|---|---|---|
| INFORMATION ON STOCK OPTIONS | | | | | |
| Date of General Meeting | 06/11/2014 | 05/04/2016 | 05/03/2017 | 10/05/2018 | 10/05/2018 |
| Date of the Board of Directors' meeting | 09/01/2014 | 07/26/2016 | 02/28/2018 | 11/12/2018 | 05/19/2019 |
| Total number of shares able to be subscribed for or bought including the number able to be subscribed for or bought by corporate officers: | 120,000 | 115,000 | 55,000 | 40,000 | 170,000 |
| Start date for exercise of the options | 09/01/2015 | 07/26/2017 | 02/28/2019 | 11/12/2019 | 05/19/2020 |
| Expiration date | 09/01/2024 | 07/26/2026 | 02/28/2028 | 11/12/2028 | 05/19/2029 |
| Issue price | €0.61 | €0.16 | €0.30 | €0.28 | €0.17 |
| Exercise price | €6.12 | €1.68 | €3.12 | €2.76 | €1.84 |
| Exercise procedures (where the plan consists of several tranches) | In thirds every 3 years | In thirds every 3 years | In thirds every 3 years | In thirds every 3 years | In thirds every 3 years |
| Number of shares subscribed at 12/31/2019 | N/A | N/A | N/A | N/A | N/A |
| Cumulative number of stock options canceled or invalid | 60,000 | 25,000 | 0 | 0 | 0 |
| Stock options remaining at financial year-end | 60,000 | 90,000 | 55,000 | 40,000 | 170,000 |

| Stock options granted to the top ten employees who are not corporate officers and options exercised by them | Total number of options granted/shares subscribed for or bought | Weighted average price | Plan No. X | Plan No. X |
|---|---|---|---|---|
| Options granted during the period by the issuer and by any company within the scope of the option grant, to the ten employees of the issuer and any company within that scope granted the highest number of options (aggregate information)<br><br>Options held on the issuer and the companies referred to above, exercised during the period by the ten employees of the issuer and such companies having bought or subscribed for the highest number of options (aggregate information) | N/A | | | |

| Historical bonus preference share grants | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Information on bonus preference shares granted | | | | | | | | |
| Date of General Meeting | 05/04/16 | 05/04/16 | 05/04/16 | 10/05/18 | 10/05/18 | 10/05/18 | 10/05/18 | 10/05/18 |
| Date of the Board of Directors' meeting | 07/26/16 | 11/15/16 | 10/17/17 | 10/10/18 | 11/12/18 | 09/19/19 | 11/20/19 | 04/27/20 |
| Total number of bonus shares granted | 7,765 | 570 | 2,340 | 5,700 | 1,375 | 150 | 400 | 100 |
| Share vesting date | 07/26/17 | 11/15/17 | 10/17/18 | 10/10/19 | 11/12/19 | 09/19/20 | 11/20/20 | 04/27/21 |
| Expiration of the holding period | 07/26/19 | 11/15/19 | 10/17/20 | 10/10/21 | 11/12/21 | 09/19/22 | 11/20/22 | 04/27/23 |
| Number of shares subscribed for | - | - | - | - | - | - | - | - |
| Cumulative number of shares canceled or invalid | 1,850 | 350 | 1,990 | na | 300 | 150 | na | na |
| Bonus preference shares remaining at year-end | 5,915 | 220 | 350 | 5,700 | 1,075 | 0 | 400 | 100 |

## 15.2 Amounts allocated by the Company for the purposes of paying pensions and retirement and other benefits to directors and executives

The Company has not allocated any amounts for the purposes of paying pensions, retirement and other benefits to directors and executives.

The Company has not granted any signing or departure bonuses to these persons.

## 15.3 Options granted to directors and executives

The following table shows, as of the filing date of this Universal Registration Document, all share warrants (BSA), founders' warrants (BSPCE), stock options and free performance shares (AGAP) issued by the Company to its corporate officers and executives, whether subscribed for by the beneficiaries or not during the 2019 financial year:

| Beneficiaries | | BSA | Founders' warrants (BSPCE) | Stock options | AGAP |
|---|---|---|---|---|---|
| Alexandre Loiseau | Chief Executive Officer until October 22, 2018 then Chairman of the Board of Directors as of that date | | | | |
| Joseph DeVivo | Director | 40,000 | | | |
| Christopher McFadden | Independent director, Chairman of the Board of Directors through October 22, 2018 | 50,000 | | | |
| Jennifer F Tseng | Director | 40,000 | | | |
| Molly O'Neill | Director | 40,000 | | | |
| Robert Gershon | Chief Executive Officer as of October 22, 2018 | | | | |
| Christophe Lamboeuf | Deputy CEO as of October 22, 2018 | | | | |

The exercise of each share warrant entitles the holder to one new share; the exercise of each preference share entitles the holder to a maximum of 100 new shares.

For a detailed description of the features of these founders' warrants, stock options and free performance shares, see 21.1.421.1.4, "Financial instruments giving access to the capital", detailing the various plans still current as of the filing date of this Universal Registration Document.

# SECTION 16
# 16. FUNCTIONS OF ADMINISTRATIVE AND EXECUTIVE BODIES

## 16.1 Company management

Details on the members of the Board of Directors are given in Section 14.1.1

During the financial year 2019, the Company's Board of Directors met seven times on February 7, March 19, May 19, July 25, September 19, November 20 and December 13. All meetings were chaired by the Chairman of the Board. The directors' attendance rate was close to 97%.

Exercise of General Management of the Company

In a decision dated May 25, 2011, the Board of Directors chose to separate the functions of Chairman and Chief Executive Officer.

At the Board of Directors meeting of October 10, 2018, with effect from October 22, 2018, Mr. Alexandre Loiseau was appointed Chairman of the Board of Directors representing the Company with respect to third parties. As part of his appointment, he was assigned specific tasks, in particular for the 2019 financial year:

- Serve as a resource and assist the Chief Executive Officer, at his request, in operational or strategic initiatives as well as in the transition to his position;
- Serve as a resource and assist the team in charge of developing the application in interventional pulmonology and assist in the coordination of various initiatives;
- Serve as a resource and assist the product development manager on the product roadmap;
- Assist the team in charge of intellectual property to strengthen the Company's position in this field;
- Help maintain high-level relationships with opinion leaders in multiple fields as well as strategic partners and/or suppliers;
- Serve as a resource on various strategic initiatives including development in China;
- Serve as a resource on obtaining reimbursement in France for various applications.

At the Board of Directors meeting of October 10, 2018, with effect from October 22, 2018, Mr. Robert L. Gershon was appointed Chief Executive Officer. The Chief Executive Officer is not subject to any limit of powers implemented by the Board of Directors. He is assisted in his duties by a Deputy CEO, Mr. Christophe Lamboeuf, who is vested with the same powers as the CEO and is also the Company's Chief Financial Officer.

Mr. Christophe Lamboeuf succeeded Mr. Olivier Regnard as Chief Financial Officer as of April 5, 2018. He was then appointed Deputy CEO, while maintaining his role as CFO, at the Board of Directors meeting of October 10, 2018 with effect from October 22, 2018. With 25 years of experience in finance, accounting and operations, he is directly in charge of the Finance, Information Systems, Human Resources and Operations departments at the Group level.

Information on agreements between executives and the Company

As of the date of this Universal Registration Document, there were no agreements between executives and the Company.

## 16.2 Specialized committees – Corporate governance

In accordance with recommendation No. 6 of the MiddleNext Code, the Board of Directors decided to set up three specialized committees: the Audit Committee, the Compensation Committee and the Strategic Committee.

### 16.2.1 Audit Committee

**Composition**

In the meeting of May 25, 2011, the Board of Directors established an Audit Committee, the members of which adopted the internal rules described below.

The Audit Committee is, if possible, comprised of at least three members appointed by the Board of Directors. The term of service of Audit Committee members is the same as that of their directorships.

The members of the Audit Committee are chosen from among the members of the Board of Directors and, to the extent possible, two-thirds of them are independent directors, one of them having particular competence in financial or accounting matters, with the understanding that all the members have minimum competence in financial or accounting matters.

The members of the Audit Committee are as follows:

- Molly O'Neill, Chairwoman and independent director, appointed by the Board of Directors meeting of October 10, 2018;
- Joseph DeVivo, member of the Audit Committee, appointed by the Board of Directors on March 23, 2016.

The appointment of two members was deemed sufficient in view of the total number of Directors of the Company. The internal rules of procedure of the Audit Committee, adopted on May 25, 2011 after approval by the Board of Directors, outline the legal responsibilities and practices of the Audit Committee, including the minimum number of committee meetings each year. They also state that the Committee may interview any member of the Company's Board of Directors and request any internal or external audit for any matter that it considers within its remit. The Chairman of the Audit Committee shall give prior notice of this act to the Board of Directors. In particular, the Audit Committee has the authority to hear persons who participate in the preparation of the financial statements or their review (Vice President of Finance, Director of Administration and Finance). It has the right of direct, independent and confidential consultation with the statutory auditors.

**Responsibilities**

The Audit Committee is responsible in particular for:

- monitoring the process of preparing the financial information;
- monitoring the efficacy of the internal control and risk management systems;
- monitoring the legal audit of the annual financial statements and the consolidated financial statements by the statutory auditors;
- issuing a recommendation on the statutory auditors proposed for appointment by the Annual General Meeting and reviewing the terms of their compensation;
- monitoring the independence of the statutory auditors;
- examining the conditions for the use, if any, of derivatives;
- periodically reviewing the status of major litigation; and
- in general, providing any advice and making any appropriate recommendation in the above areas.

The Audit Committee met twice during the 2019 financial year.

### 16.2.2 Compensation Committee

The Compensation Committee is responsible in particular for:

- examining the main objectives proposed by General Management with respect to the compensation of executives who are not corporate officers of the Group, including the bonus share and stock option plans;
- examining the compensation of executives who are not corporate officers, including the bonus share and stock option plans, the pension and insurance benefit plans and the benefits in kind;
- making recommendations and proposals to the Board of Directors on:
    - the compensation, the pension and insurance benefit plans, the benefits in kind, the other financial rights, including those in the event of retirement, of the members of the Board of Directors. The committee proposes compensation amounts and structures, in particular, rules for determining the variable portion, taking into account the Company's strategy, objectives and results as well as market practices, and
    - the bonus share and stock option plans and any other similar profit-sharing arrangement, in particular, the personal awards to the members of the Board of Directors;
- examining the total amount of directors' fees and the arrangements for distribution among the members of the Board of Directors, as well as the conditions for reimbursement of expenses that might have been incurred by the members of the Board of Directors;
- preparing and presenting the reports, where applicable, set forth in the Board of Directors' internal rules of procedure, and;
- preparing any other recommendation that might be asked of it by the Board of Directors with respect to compensation.

In general, the Committee provides any advice and makes any appropriate recommendation in the above areas.

The Compensation Committee consists if possible of at least two members appointed by the Board of Directors, with the provision that no member of the Board of Directors who serves as an executive in the Company can serve on the Committee. The term of service of Compensation Committee members is the same as that of their directorships.

It is stated to the extent necessary that no member of the Board of Directors who carries out executive duties in the Company may be a member of the Compensation Committee.

The members of the Compensation Committee appointed on June 11, 2014, March 21, 2017 and October 10, 2018 are:

- Mr. Chris McFadden, Chairman of the Compensation Committee and independent director;
- Mr. Alexandre Loiseau, independent director;
- Ms. Jennifer F. Tseng, independent director.

As part of its duties, the Committee may ask the Chairman of the Board of Directors to obtain assistance from any Company executive whose expertise might facilitate the handling of any item on the agenda.

The Committee met three times during the 2019 financial year.

#### 16.2.3 Strategic Committee

The Strategic Committee constituted by the Board of Directors of October 10, 2018 is responsible for making recommendations to the Board on the Company's strategic approaches.

It is comprised of three members: Messrs. Alexandre Loiseau, Robert Gershon and Joseph DeVivo.

The Committee met once during the 2019 financial year.

## 16.3 Statement relating to corporate governance

In the interests of transparency and public information, the Company has embarked on a comprehensive review of its corporate governance practices.

In view of the Company's organization, its size and resources, it has decided to refer to the MiddleNext Corporate Governance Code for small- and mid-caps, published on December 17, 2009 (the MiddleNext Code), with effect from the admission to trading of the Company's shares on the NYSE Euronext Paris market.

To meet the corporate governance standards that the Company has set itself, the following measures have already been put in place.

| Recommendations of the MiddleNext Code | Already adopted | Will be adopted | Will not be adopted | Under consideration |
|---|---|---|---|---|
| **I. Supervisory power** | | | | |
| R1 - Code of conduct for Board members | X | | | |
| R2 - Conflicts of interest | X | | | |
| R3 - Composition of the Board - Presence of independent members | X | | | |
| R4 - Information for Board members | X | | | |
| R5 - Organization of Board and Committee meetings | X | | | |
| R6 - Formation of committees | X | | | |
| R7 - Adoption of Board internal rules | X | | | |
| R8 - Choice of each Board member | X | | | |
| R9 - Term of office of Board members | X | | | |
| R10 - Compensation of Board members | X | | | |
| R11 - Evaluation of the Board's work | X | | | |
| R12 - Shareholder relations | X | | | |
| **II. Executive power** | | | | |

| Recommendations of the MiddleNext Code | Already adopted | Will be adopted | Will not be adopted | Under consideration |
|---|---|---|---|---|
| R13 - Definition and transparency of compensation of executive officers | X | | | |
| R14 - Manager succession planning | X | | | |
| R15 - Concurrent employee and corporate officer status | X | | | |
| R16 - Severance | X | | | |
| R17 - Supplementary pension plans | X | | | |
| R18 - Stock options and bonus shares | X | | | |
| R19 - Review of vigilance points | X | | | |

## 16.4 Report of the Chairman on internal controls

In accordance with the provisions of Article L. 225-37 of the French Commercial Code, the Chairman of the Board of Directors prepares a report on internal control accounting for the composition, conditions of preparation and organization of the Board's work and the internal control and risk management procedures put in place by the Company.

The first part of the Chairman's report covers the operations of the Board of Directors and the specialized committees described in Section 16 Below is an extract from the report corresponding to the section on internal control.

**EXTRACT FROM THE REPORT BY THE CHAIRMAN OF THE BOARD OF DIRECTORS ON CORPORATE GOVERNANCE, INTERNAL CONTROL AND RISK MANAGEMENT**

**2.1. General principles of risk management**

A) Definition

Mauna Kea Technologies continues to formalize its risk management process.

This process aims to identify all the risks and risk factors that can impact the Company's business activities and operations and to define the means of managing such risks and of containing them or bringing them down a level the Company can accept. The aim is to encompass every type of risk and apply the process to every activity of the Company and the Group.

B) Objectives of risk management

Mauna Kea Technologies has adopted the definition of risk management proposed by the Autorité des Marchés Financiers[19] (the French Financial Markets Authority), whereby risk management is one of the Company's management tools that helps to:

- create and preserve the Company's value, assets and reputation;
- safeguard the Company's decision making and processes to promote the achievement of its objectives;
- ensure the Company's actions are consistent with its values;
- engage the employees around a common vision of the Company's principal risks.

C) Components of the risk management system

The risk factors identified to date by the Company are presented in Section 4 4of this Universal Registration Document.

To date, the Company has identified the following major families of risk:

- Risks related to the markets in which the Company operates;
- Legal risks (regulation applicable to medical devices and to authorizations already obtained or to ongoing processes and to the regulatory environment, intellectual property, product liability claims, etc.);
- Financial risks;
- Risks related to the Company's business and organization.

**2.2. Co-ordination between risk management and internal control**

The point of risk management is to identify the major risks and risk factors that might impact the activities, processes or objectives of the business and to define the means of containing these risks at an acceptable level, including by adopting preventive measures and controls that fall within the scope of the internal control system.

At the same time, the internal control system relies primarily on the risk management system to identify the major risks that need to be controlled. The Company devised and developed an internal control system from its initial founding, while the formalization of a risk management process has been more recent. The Company is now engaged in a process of coordinating the two systems, with the primary goal of identifying the control procedures that must apply to the business's key activities which might be affected by risks that analysis shows to be "major".

**2.3. General principles of internal control**

A) Definition

Mauna Kea Technologies adopts the definition of internal control proposed by the Autorité des Marchés Financiers[20] (the French Financial Markets Authority), whereby internal control is a system implemented by the Company to ensure:

compliance with laws and regulations;
the enforcement of instructions and guidelines set by general management;
the proper functioning of the Company's internal processes;
the reliability of financial information, and in general contributes to the management of its activities, the efficacy of its operations and the efficient utilization of its resources.

[19]Guide to the implementation of the reference framework for internal control adapted to small- and mid-caps (updated on July 22, 2010).

[20]Guide to the implementation of the reference framework for internal control adapted to small- and mid-caps (updated on July 22, 2010).

During the financial year, Mauna Kea Technologies continued to apply an internal control process designed to "guarantee internally the relevance and reliability of the information used and disseminated in the Company's activities".

B) The components of internal control

Organization of the validation system

The internal control system is based on a clear organization of responsibilities, guidelines, resources and procedures. The Company has always had a quality assurance system. The processes applied in all areas of the business are defined in written procedures, operating methods, forms and notices. These documents outline the workflow, define the resources and responsibilities of participants, specify the know-how of the Company and give precise instructions on how to perform a given operation.

In 2013, to enhance its quality system and internal control, the Company opted to introduce SAP integrated management software with a pre-configured package designed for small and medium-sized enterprises. The functions concerned by this software are Purchasing/Suppliers, Sales/Customers, Accounts and Management Control.

Every year, the Company is the subject of a systems-information audit. The last audit completed in 2018 did not reveal significant anomalies.

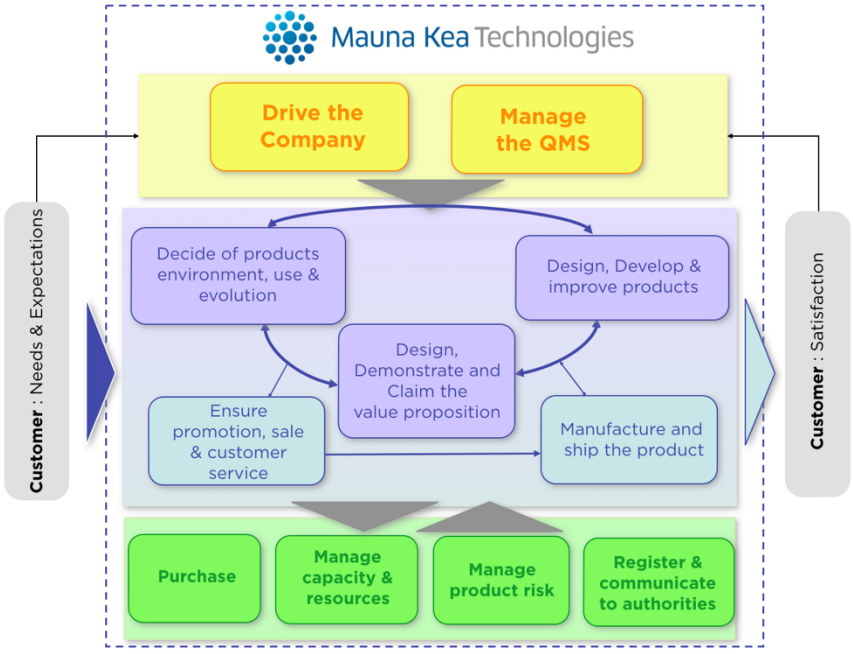
Everyone in the Company is affected by the internal control system.

Procedures relating to operational processes

All documentation relating to the quality management system (QMS) is stored on a dedicated intranet which optimizes access to the documents and their ongoing adaptation to business developments (document life cycle management). The aim is to foster a continuous improvement in the quality and functional processes of the Company and the Group, be they operational, management or support processes.

Each one of these processes is placed under the responsibility of a steering person, who manages, along with responsibility for quality, all of the quality-control procedures and forms describing the activities covered by the process, as well as the performance indicators connected to the process. The various processes are reviewed on a regular basis by the corporate management, at the time of the management's review.

The quality assurance system covers the following areas:




The quality management system is audited once yearly by the notified entity GMED within the framework of the CE marking for medical devices. Since 2017, the results of the annual follow-up audits have shown by the lack of non-compliance, that the quality system has come of age. CE marking has been ensured and maintained since its first certification. Furthermore, in 2018, the Company's quality system has been inspected by the FDA according to the requirements of 21 CFR 820. The result was positive, and while only one instance of non-compliance was revealed, corrective action was quickly defined, and this outcome did not jeopardize the U.S.

marketing authorizations. The Company provides to its day-to-day operations the level of efficiency needed to maintain compliance with the requirements to which it is subject, involving all its employees.

Financial reporting procedures

The Company has set up the following organization to limit financial management risks:

- The Company's General Management, and more specifically staff from the Finance department, are responsible for improving internal control and adopting the recommendations of the external auditors and Audit Committee;
- The Company maintains an internal separation between the production and supervision of its financial statements and relies on independent experts to examine complex accounting entries such as the Research Tax Credit and valuation of stock options or founders' warrants;
- A certified public accountant is in charge of preparing the consolidated financial statements under IFRS;
- The financial and accounting management of the U.S. subsidiary, Mauna Kea Technologies Inc., undergoes a regular internal review by the registered office accounting team;
- Payroll management in France and the review of U.S. payroll is outsourced to a specialized independent firm.

In general, all of the Company's accounting options are defined by the Finance department following a discussion with the General Management and Statutory Auditors, before being presented to and examined jointly with the Audit Committee. This ensures that the Company's practices are fully compliant with French and international standards (IFRS), as well as maintaining consistency in the presentation of the financial statements.

At year-end, a detailed budget is prepared for the following financial year by the Finance Department and signed off by the General Management. This budget is presented to the Board of Directors. At the end of each half-year, the accounting teams close the consolidated accounts of Group companies.

The analytical validation of entries and a comprehensive spending review are carried out during periodic budget reviews organized with all operational managers. The Finance Department reports to the General Management and directors at each Board meeting. The reports are presented and discussed periodically at Board meetings.

**2.4. Risk management and internal control actors**

Since the Company's inception, the General Management has always played a key role in defining and driving the internal control and risk management system.

**2.5. Risk management and internal control limits and opportunities for improvement**

The Company seeks to adapt its risk management system to its information system (ERP) and to improve the monitoring of the action plans identified.

In the medium term, the Company could extend the functional coverage of its ERP system with additional functions such as production and after-sales service.

# SECTION 17
# 17. EMPLOYEES

## 17.1 Human resources

### 17.1.1 Presentation of employees


**Annual Average Workforce** **Permanent contract** **Executive workforce**

The workforce is almost exclusively on permanent contracts. The headcount is highly qualified, and consists primarily of executives. The Company mainly hires people with high-level education and skills, and also invests significantly in training new employees, with a view to retaining them.

### 17.1.2 Number and workforce distribution

Distribution of average annual workforce by category:

| | 12/31/19 | 12/31/18 | Change |
|---|---|---|---|
| Permanent contract | 97.3 | 95.4 | +2.0% |
| Fixed-term contract | 4.1 | 1.3 | +215.4% |
| Apprentices | 0.8 | 2.8 | -71.4% |
| Total workforce | 102.2 | 99.5 | +2.7% |
| Executives | 89.8 | 86.8 | +3.5% |
| Non-executives | 12.4 | 12.7 | -2.4% |

Breakdown of the average annual workforce by gender:

| | 12/31/19 | 12/31/18 | Change |
|---|---|---|---|
| Men | 64.0 | 61.6 | +3.9% |
| Women | 38.2 | 37.9 | +0.8% |
| **Total workforce** | **102.2** | **99.5** | **+2.7%** |

Distribution of the annual average workforce by geographical region:

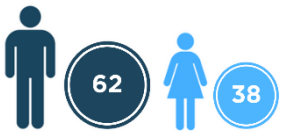
| | 12/31/19 | 12/31/18 | Change |
|---|---|---|---|
| France | 72.2 | 72.1 | +0.1% |

| | | | |
|---|---|---|---|
| Europe excluding France | 0.90 | 0 | - |
| America | 26.1 | 24.5 | +6.5% |
| Asia-Pacific | 3.0 | 2.9 | +3.4% |
| **Total workforce** | **102.2** | **99.5** | **+2.7%** |

Entries and departures:

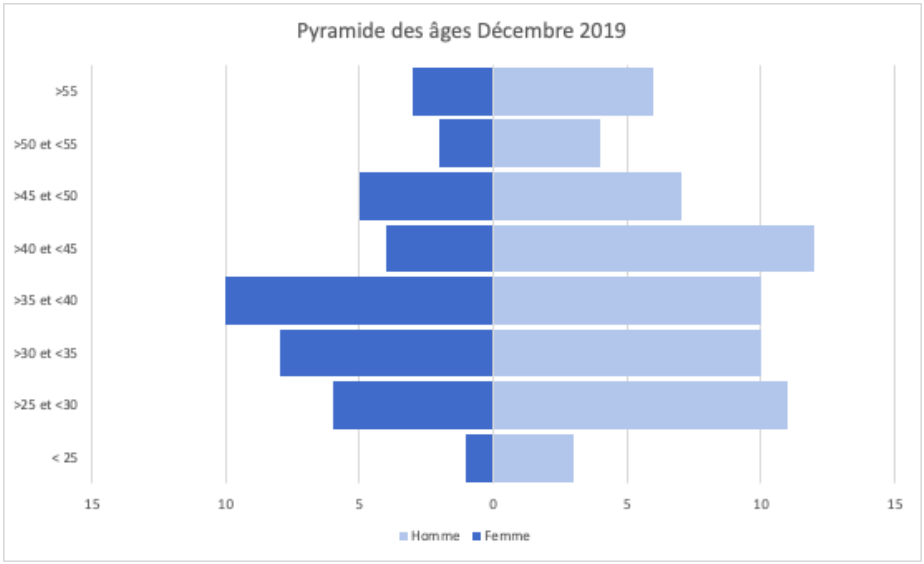
| Number of new hires | 2019 | 2018 | 2017 |
|---|---|---|---|
| Permanent contracts | 16 | 36 | 33 |
| Fixed term contracts | 8 | 1 | 7 |
| Apprentice/intern | 1 | 0 | 5 |
| **Total** | **25** | **37** | **45** |

| Departure by reason | 2019 | 2018 |
|---|---|---|
| Redundancies/dismissals | 2 | 1 |
| Voluntary departure | 14 | 19 |
| End of fixed-term contract | 2 | 1 |
| Others | 2 | 6 |
| **Total** | **20** | **27** |

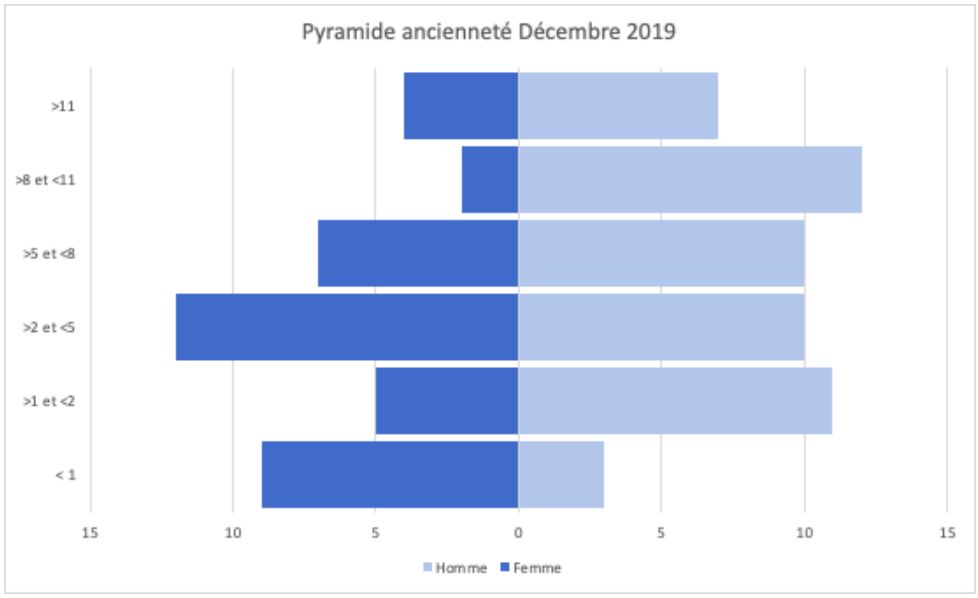



In France, recruitment has occurred in both operational functions and management functions, with the same stabilization and strengthening objective.

Although Mauna Kea has more men than women, the latter are well represented in all functions of the Company. Their representation increased from the previous year.




26% of employees are over age 45 and 21% are under 30, with proportions that remain stable from year to year and demonstrate the Company's ability to attract talent from all levels of experience and maintain a broad diversity of age in its workforce.




The 2019 length of service pyramid shows the impact of recruiting in the last two years: the 0-2 year bracket now makes up 45% of the workforce (all sexes together), which confirms the Company's ability to attract new talent. Consequently, the median tranche (2 to 8 years of service) dropped slightly in terms of proportion.

Moreover, the number of employees with more than eight years of service is growing slightly, a sign of employees' commitment and consistent adherence to the Company's values.

There was also a decline in departures in the less than one year bracket. The improved Human Resources process implemented in 2018 has begun to bear its fruits. Stabilizing Mauna Kea Technologies' teams remains a Human Resources priority.

### 17.1.3 Organization of work hours

The majority of employees work on a daily contract basis, pursuant to the contractual framework, which allows them a contractual number of rest days (9 in 2019).

Other employees work on a basis of 36 hours and 50 minutes per week, also benefiting from 9 rest days (in 2019).

The majority of employees work full time: throughout 2019, only 0.3 employees were part-time.

Absenteeism (excluding paternity and maternity leave)

| Scope - France only<br>Excluding work-study students | 2019 | 2018 |
|---|---|---|
| Number of sick days / total number of hours theoretically worked | 1.52% | 1.22% |

Absenteeism was stable within the Company. This remains well below the national average observed by specialized firms (Ayming reports 5.10% average absenteeism in 2019 in France).

Increased access to teleworking, paid paternal leave and the allocation of rest days in 2014 has helped boost this indicator.

### 17.1.4 Values shared by employees

Working at Mauna Kea Technologies is much more than the simple performance of assigned tasks. The Company expects from each employee a faultless work ethic: honesty, openness, good humor and respect are the key values shared by all on a daily basis. Motivation, initiative, and creativity are also expected, at the cost, if necessary, of risk-taking, mistakes, or actions being called into question, but always attentive to new proposals. Innovation does not follow a straight and well-trodden path. To innovate, it is essential to know how to take risks, explore, make mistakes, question oneself, listen, and change.

Employees have now jointly defined and share a system of values, which make for a strong business. This system relies upon four pillars:

passion for performance;
thinking outside the box;
the willingness to grow with the business;
team solidarity.

These four values structure and provide direction to the work and daily exchanges between employees, as does the quality-control policy, of which they form an integral part.

## 17.2 Equity stakes and stock options of directors and executives

As of the date of this Universal Registration Document, the direct and indirect equity stakes of the members of the Board of Directors and the number of financial instruments granting access to the Company's share capital that they hold are as follows:

| Names | Shares | | Financial instruments |
|---|---|---|---|
| | In numbers | % of the capital | giving access to capital |
| Alexandre Loiseau | 511,740 | 1.67% | 100,000 BSPCE 2014 to be exercised at the rate of 1 BSPCE 2014 for one new 21.1.4see Section 21.1.4 of this Universal Registration Document for the exercise conditions)<br><br>1,600 Preference Shares 2016 at the rate of 1 preference share for 100 new shares<br><br>4,500 Preference Shares 2018 at the rate of 1 preference share for 100 new shares |
| Christopher McFadden | - | - | 30,000 BSA 2014<br>40,000 BSA 2016<br>40,000 BSA 2018<br>50,000 BSA 2019 |
| Joseph DeVivo | - | - | 25,000 BSA 2016<br>40,000 BSA 2019 |
| Jennifer F. Tseng | - | - | 30,000 BSA 2018<br>40,000 BSA 2019 |
| Molly O'Neill | - | - | 25,000 BSA 2018<br>40,000 BSA 2019 |
| Rob Gershon | - | - | 600,000 2018 Stock Options |
| Christophe Lamboeuf | - | - | 1,200 Preference Shares 2018 at the rate of 1 preference share for 100 new shares |

## 17.3 Employee participation in Company share capital

At December 31, 2019, Group employees held 26,775 shares and 53,550 voting rights, i.e. 0.09% of the Company's capital and 0.17% of its voting rights.

## 17.4 Profit-sharing and participation agreements

N/A.

# SECTION 18
# 18. PRINCIPAL SHAREHOLDERS

## 18.1 Breakdown of the capital and voting rights

**Changes in the breakdown of the capital and voting rights**

| Shareholders | 12/31/2019 | | | | | | 12/31/2018 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of share | % of share capital | Number of theoritical voting rights | % of theoritical voting rights | Voting rights exercisable at GMS | % voting rights exercisable at GMS | Number of share | % of share capital | Number of theoritical voting rights | % of theoritical voting rights | Voting rights exercisable at GMS | % voting rights exercisable at GMS |
| Alexandre Loiseau | 511 740 | 1,67% | 1 023 480 | 3,23% | 1 023 480 | 3,23% | 511 740 | 2,03% | 1 023 480 | 3,89% | 1 023 480 | 3,89% |
| **Subtotal Board of Directors** | **511 740** | **1,67%** | **1 023 480** | **3,23%** | **1 023 480** | **3,23%** | **511 740** | **2,03%** | **1 023 480** | **3,89%** | **1 023 480** | **3,89%** |
| Seventure (nominatif) | | | | | | | | | | | | |
| Seventure (*) | | | | | | | | | | | | |
| Inocap | | | | | | | | | | | | |
| Johnson & Johnson Inncovation - JJDC Inc | 5 357 142 | 17,52% | 5 357 142 | 16,91% | 5 357 142 | 16,93% | | | | | | |
| **Subtotal major shareholders** | **5 357 142** | **17,52%** | **5 357 142** | **16,91%** | **5 357 142** | **16,93%** | **0** | **0,00%** | **0** | **0,00%** | **0** | **0,00%** |
| Other registered | 638 510 | 2,09% | 1 251 913 | 3,95% | 1 251 913 | 3,96% | 636 769 | 2,53% | 1 250 193 | 4,75% | 1 250 193 | 4,76% |
| Other free float | 24 028 562 | 78,60% | 24 015 302 | 75,80% | 24 015 302 | 75,88% | 24 014 010 | 95,29% | 24 014 010 | 91,22% | 24 014 010 | 91,35% |
| Own shares | 35 786 | 0,12% | 35 786 | 0,11% | 0 | 0,00% | 38 819 | 0,15% | 38 819 | 0,15% | 0 | 0,00% |
| **Total shares comprising the share capital** | **30 571 740** | **100,00%** | **31 683 623** | **120,14%** | **31 647 837** | **120,16%** | **25 201 338** | **100,00%** | **26 326 502** | **100,00%** | **26 287 683** | **100,00%** |

| Shareholders | 12/31/2017 | | | | | | 12/31/2016 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number of share | % of share capital | Number of theoritical voting rights | % of theoritical voting rights | Voting rights exercisable at GMS | % voting rights exercisable at GMS | Number of share | % of share capital | Number of theoritical voting rights | % of theoritical voting rights | Voting rights exercisable at GMS | % voting rights exercisable at GMS |
| Alexandre Loiseau | 511 740 | 2,10% | 1 023 480 | 3,91% | 1 023 480 | 3,91% | 549 240 | 2,75% | 1 075 080 | 4,99% | 1 075 080 | 4,99% |
| **Subtotal Board of Directors** | **511 740** | **2,10%** | **1 023 480** | **3,91%** | **1 023 480** | **3,91%** | **549 240** | **2,75%** | **1 075 080** | **4,99%** | **1 075 080** | **4,99%** |
| Seventure (nominatif) | 99 006 | 0,41% | 198 012 | 0,76% | 198 012 | 0,76% | 396 012 | 1,98% | 792 024 | 3,67% | 792 024 | 3,68% |
| Seventure (*) | | | | | | | 110 892 | 0,55% | 110 892 | 0,51% | 110 892 | 0,51% |
| Inocap | | | | | | | 1 760 175 | 8,80% | 1 760 175 | 8,16% | 1 760 175 | 8,17% |
| Johnson & Johnson Inncovation - JJDC Inc | | | | | | | | | | | | |
| **Subtotal major shareholders** | **99 006** | **0,41%** | **198 012** | **0,76%** | **198 012** | **0,76%** | **2 267 079** | **11,33%** | **2 663 091** | **12,35%** | **2 663 091** | **12,36%** |
| Other registered | 619 644 | 2,55% | 619 644 | 2,37% | 619 644 | 2,37% | 702 691 | 3,51% | 1 339 857 | 6,21% | 1 339 857 | 6,22% |
| Other free float | 23 098 801 | 94,87% | 23 098 801 | 88,23% | 23 098 801 | 88,29% | 18 107 090 | 90,53% | 18 107 090 | 83,98% | 18 107 090 | 84,07% |
| Own shares | 18 147 | 0,07% | 18 147 | 0,07% | 0 | 0,00% | 23 681 | 0,12% | 23 681 | 0,11% | 0 | 0,00% |
| **Total shares comprising the share capital** | **24 347 338** | **102,51%** | **26 179 576** | **100,00%** | **26 161 429** | **100,00%** | **20 001 838** | **100,00%** | **21 561 156** | **100,00%** | **21 537 475** | **100,00%** |

(*) Bearer shares.

To the knowledge of the Company, no action in concert between shareholders exists.

## 18.2 Significant shareholders not represented on the Board of Directors

At December 31, 2019, Johnson & Johnson Innovation Inc. held an equity investment of 17.5% and is not represented on the Company's Board of Directors.

## 18.3 Voting rights of the principal shareholders

By a decision of the General Meeting dated May 25, 2011, a double voting right was created for all the shares held in registered form for at least three years in the name of the same shareholder.

Voting rights attached to shares are proportional to the percentage of the capital they represent and each share confers the right to at least one vote.

However, under Article 9 of the bylaws and in accordance with the provisions of the French Commercial Code, all fully paid-up shares which are proven to have been registered for at least three years in the name of the same shareholder qualify for double the voting rights of other shares in view of the percentage of the share capital they represent.

At December 31, 2019, the following shareholders were eligible for double voting rights:

| Shareholders | Double voting rights |
|---|---|
| ALEXANDRE LOISEAU | 1,023,480 |
| FUJIKURA | 424,882 |
| CREDIT AGRICOLE LUXEMBOURG | 229,238 |
| IPERIUM INTRENATIONAL | 154,994 |
| Various individuals and legal entities | 442,799 |
| TOTAL | 2,275,393 |

Statutory restrictions on the exercise of voting rights and the transfer of shares or clauses brought to the Company's attention in application of Article L. 233-11 of the French Commercial Code.

N/A.

Direct or indirect stakes in the Company's share capital of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code.

See 15.1.115.1.1 above: Restrictions imposed by the Board in respect of the exercise of options granted or sale of bonus shares granted to executives.

## 18.4 Participation of shareholders in Annual General Meetings

In accordance with recommendation No. 12 of the MiddleNext Code, the Board hereby reports on the Company's shareholder relations.

**Combined General Meeting of 2019**

The Company held a Combined General Meeting on July 5, 2019 at the Company's head office, in accordance with Article 19 of the Company's bylaws. Shareholders present or represented by proxy accounted for 22% of the Company's share capital and 26% of its voting rights (according to the number of shares making up the capital minus Treasury shares). Shareholders were able to vote by absentee ballot or proxy or attend the Meeting in person. The ordinary resolutions were all adopted with more than 94% of votes (with the exception of resolution 12 related to the appointment of a non-voting Board member which was rejected). All resolutions were approved by a majority of more than 88% (except for Resolution 16 which was rejected and which the Board of Directors had advised voting against).

**Combined General Meeting of 2020**

The Company held a Combined General Meeting on July 2, 2020.

In view of the state of health emergency in force until July 10, 2020, in accordance with Article 4 of Decree No. 2020-418 of April 10, 2020 covering the rules for meetings and deliberations of the meetings and governing bodies of legal entities and unincorporated entities under private law due to the Covid-19 epidemic, the Company's head office, located at 9 rue d'Enghien, 75010 Paris, the Annual General Meeting location, was impacted on the date of the Annual General Meeting by the provisions of Decree No. 2020-663 of May 31, 2020 prescribing the general measures necessary to confront the Covid-19 epidemic as part of the state of health emergency. In this context, in accordance with Article 4 of the ordinance no. 2020-321 of March 25, 2020, the Board of Directors decided to hold the Annual General Meeting in camera, without the physical presence of shareholders, at the Company's head office.

Shareholders present or represented comprised 26.83% of the Company's voting rights. Given that shareholders will be unable to physically attend the meeting, the latter were able to give a proxy to the Chairman or vote by absentee ballot using the form provided for this purpose, which can be downloaded from the Company's website from the twenty-first business day prior to the meeting. Voting by absentee ballot and the proxy forms could be sent to the Company under the conditions provided for in Article 6 of Decree 2020-418 of April 10, 2020.

The ordinary resolutions were all adopted with more than 97% of votes. The ordinary resolutions were all adopted with more than 72% of votes.

The terms for taking part in general meetings are set out in Article 19 of the bylaws, available online at www.maunakeatech.com.

The right to participate in the meetings shall be governed by applicable legal and regulatory provisions, and shall in particular be subject to the registration of the securities under the name of the shareholder or the proxy registered on the shareholder's behalf two (2) business days prior to the meeting at 12:00 a.m., Paris time, either in the accounts of registered securities held by the Company, or in the accounts of bearer securities held by the authorized intermediary.

Any shareholder unable to attend a meeting in person may select one of the following three options on each occasion under the legal and regulatory conditions in force:

- grant a power of attorney under the conditions authorized by law and regulations;
- vote by absentee ballot; or
- send a power of attorney to the Company, without indicating a proxy.

## 18.5 Control of the Company

As of the date of this Universal Registration Document, no single shareholder holds a high enough percentage to presume control of the Company as defined by the provisions of Article L. 233-3 of the French Commercial Code.

The Company has thus not implemented measures to guarantee that this control is not exercised abusively.

To the knowledge of the Company, no action in concert between shareholders exists.

## 18.6 Agreement that may cause a change in control

No specific item in the articles of incorporation, bylaws, charter or rules of the issuer could have the effect of delaying, deferring, or preventing a change in its control.

## 18.7 Statement of pledges

See Section 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses- Note 21

# SECTION 19
# 19. TRANSACTIONS WITH RELATED PARTIES

The existing regulated agreements as of this date are mentioned in the special reports of the statutory auditors presented below.

## 19.1 Intra-group transactions

The intra-group transactions are described in 7.37.3 "Principal intra-group flows" of this Universal Registration Document.

## 19.2 Transactions with related parties

See Section 14.2of this Universal Registration Document.

## 19.3 Assessment procedure of current regulated agreements

In accordance with Article L. 225-39 paragraph 2 of the French Commercial Code, as amended by Law no. 2019-486 of May 22, 2019 relating to the growth and transformation of companies (known as the "Pacte Law"), the Board of Directors is required to implement a procedure to regularly assess whether the agreements covering current operations and entered into under normal conditions fulfill these conditions.

A draft internal charter on regulated agreements and commitments and on the procedure relating to the assessment of current agreements entered into under normal conditions will be approved by the Audit Committee at its next meeting and then adopted by the Board of Directors.

The purpose of this charter will be to highlight the regulatory framework applicable to regulated agreements and commitments and set up a procedure to distinguish between agreements entered into directly or through an intermediary between the Company and the persons referred to in Article L. 225-38 of the French Commercial Code, those that are subject to the prior authorization of the Board of Directors under ordinary law and those that are likely to be considered as current within the meaning of Article L. 225-39 of the French Commercial Code and which must be regularly assessed to ensure that these agreements fulfill the conditions for this category.

## 19.4 Statutory auditors' reports on regulated agreements and commitments prepared for the financial year ended December 31, 2019

EXCO Socodec
51, avenue Françoise Giroud – Parc Valmy – BP 16601
21066 Dijon Cedex
S.A.R.L. au capital de € 3 200 000

Commissaire aux Comptes
Membre de la compagnie
régionale de Dijon

ERNST & YOUNG et Autres
1/2, place des Saisons
92400 Courbevoie - Paris-La Défense 1
S.A.S. à capital variable

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

### Mauna Kea Technologies

Annual General Meeting held to approve the financial statements for the year ended December 31, 2019

**Statutory auditors' report on related party agreements and commitments**

To the Annual General Meeting of Mauna Kea Technologies,

In our capacity as statutory auditors of your Company, we hereby present to you our report on related party agreements and commitments.

We are required to inform you, on the basis of the information provided to us, of the terms and conditions of those agreements and commitments indicated to us, or that we may have identified in the performance of our engagement, as well as the reasons justifying why they benefit the Company. We are not required to give our opinion as to whether they are beneficial or appropriate or to ascertain the existence of other agreements and commitments. It is your responsibility, in accordance with Article R. 225-31 of the French Commercial Code (Code de commerce), to assess the relevance of these agreements and commitments prior to their approval.

We are also required, where applicable, to inform you in accordance with Article R. 225-31 of the French Commercial Code (Code de commerce) of the continuation of the implementation, during the year ended December 31, 2019, of the agreements and commitments previously approved by the Annual General Meeting.

We performed those procedures which we deemed necessary in compliance with professional guidance issued by the French Institute of Statutory Auditors (Compagnie nationale des commissaires aux comptes) relating to this type of engagement.

**Agreements and commitments submitted for approval to the Annual General Meeting**

We hereby inform you that we have not been notified of any agreements or commitments authorized and concluded during the year ended December 31, 2019 to be submitted to the Annual General Meeting for approval in accordance with Article R. 225-38 of the French Commercial Code (Code de commerce).

**Agreements and commitments previously approved by the Annual General Meeting**

We hereby inform you that we have not been notified of any agreements or commitments previously approved by the Annual General Meeting, whose implementation continued during the year ended December 31, 2019.

Dijon and Paris-La Défense, April 29, 2020

The Statutory Auditors

French original signed by

| EXCO SOCODEC | ERNST & YOUNG et Autres |
|---|---|
| Olivier Gallezot | Cédric Garcia |

# SECTION 20

# 20. FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES

## 20.1 Consolidated financial statement

### 20.1.1 Consolidated financial statements prepared under IFRS for the financial year ended December 31, 2019

**STATEMENT OF FINANCIAL POSITION**
(Amounts in thousands of euros)

| | Note | 12/31/2019 | 12/31/2018 (*) |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current Assets** | | | |
| Intangible assets | **3** | 2 343 | 1 838 |
| Property, plant and equipment | **4** | 1 956 | 1 985 |
| Right of use | **4** | 1 370 | n/a |
| Non-current financial assets | **5** | 173 | 133 |
| **Total of non-current assets** | | **5 842** | **3 956** |
| **Current assets** | | | |
| Inventories & Work in progress | **6** | 2 592 | 2 456 |
| Trade receivables | **7** | 2 444 | 1 643 |
| Other current assets | **7** | 2 701 | 3 019 |
| Current financial assets | **8** | 59 | 64 |
| Cash and cash equivalents | **9** | 9 982 | 8 623 |
| **Total of current assets** | | **17 778** | **15 806** |
| **TOTAL OF ASSETS** | | **23 621** | **19 762** |

| | | 12/31/2019 | 12/31/2018 |
|---|---|---|---|
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| Issued capital | **10** | 1 223 | 1 008 |
| Share premium | **10** | 98 257 | 91 753 |
| Reserves | | (84 130) | (72 072) |
| Foreign currency translation on reserve | | 176 | 74 |
| Profit / (Loss) | | (15 272) | (12 785) |
| **Total of equity** | | **253** | **7 979** |
| **Non-current Liabilities** | | | |
| Long-term loans | **11** | 15 499 | 6 457 |
| Non-current provisions | **12** | 299 | 422 |
| **Total of non-current liabilities** | | **15 799** | **6 879** |
| **Current liabilities** | | | |
| Short-term loans and borrowings | **11** | 1 916 | 600 |
| Trade payables | **13** | 2 275 | 2 087 |
| Other current liabilities | **13** | 3 380 | 2 216 |
| **Total of current liabilities** | | **7 570** | **4 904** |
| **TOTAL OF EQUITY AND LIABILITIES** | | **23 621** | **19 762** |

(*) IFRS 16 has been applied using the simplified retrospective method, therefore the comparative period at December 31, 2018 has not been modified (see Note 1.1)

**COMPREHENSIVE INCOME**
(Amounts in thousands of euros)

| | Note | 12/31/2019 | 12/31/2018 (*) |
|---|---|---|---|
| **Operating Revenue** | | | |
| Sales | **15** | 7 431 | 6 760 |
| Other income | **15** | 1 077 | 1 141 |
| **Total of revenue** | | **8 509** | **7 901** |
| | | | |
| **Operating expenses** | | | |
| Cost of sales | | (2 260) | (2 058) |
| *Gross margin* | | *70%* | *70%* |
| Research & Development | **18** | (3 160) | (4 653) |
| Sales & Marketing | **18** | (8 978) | (9 097) |
| Administrative expenses | **18** | (6 187) | (3 953) |
| Share-based payments | **17** | (952) | (138) |
| **Total of expenses** | | **(21 537)** | **(19 899)** |
| | | | |
| **Current operating profit** | | **(13 028)** | **(11 997)** |
| | | | |
| Financial revenue | **19** | 520 | 116 |
| Financial expenses | **19** | (2 764) | (902) |
| **Profit before tax** | | **(15 272)** | **(12 785)** |
| | | | |
| Income tax expense | **20** | | |
| **Profit / (Loss)** | | **(15 272)** | **(12 785)** |
| | | | |
| **Other comprehensive income** | | | |
| ***Items that will not be reclassified to profit or loss*** | | | |
| Actuarial differences on defined benefit plans | **12** | (26) | (7) |
| **Total of items that will not be reclassified to profit or loss** | | **(26)** | **(7)** |
| ***Items that will be reclassified to profit or loss*** | | | |
| Exchange differences on translation of foreign operations | | 101 | 135 |
| **Total of items that will be reclassified to profit or loss** | | **101** | **135** |
| **Other comprehensive income for the year, net of tax** | | **75** | **127** |
| | | | |
| **Comprehensive income** | | **(15 197)** | **(12 657)** |
| | | | |
| Weighted average number of shares outstanding (in thousands) | | 25 201 | 25 201 |
| | | | |
| **Basic earnings per share (EUR / share)** | **23** | **(0,60)** | **(0,51)** |
| | | | |
| Weighted average number of potential shares (in thousands) | | 29 524 | 27 222 |

(*) IFRS 16 has been applied using the simplified retrospective method, therefore the comparative period at December 31, 2018 has not been modified (see Note 1.1)

**STATEMENT OF CHANGES IN EQUITY**
(Amounts in thousands of euros)

| | | Issued capital | Share premium | Treasury shares | Reserves | Foreign currency translation on reserve | Profit / (loss) | Total of equity |
|---|---|---|---|---|---|---|---|---|
| **Equity as of** | **12/31/2017** | **974** | **87 973** | **(84)** | **(61 812)** | **(61)** | **(10 245)** | **16 744** |
| Allocation of the profit / (loss) | | | | | (10 245) | | 10 245 | |
| Capital transactions | | 34 | 3 780 | | | | | 3 815 |
| Share-based payment transactions | | | | | 138 | | | 138 |
| Treasury shares transactions | | | | (135) | 74 | | | (61) |
| Comprehensie income as of | 12/31/2018 | | | | (7) | 135 | (12 785) | (12 657) |
| **Equity as of** | **12/31/2018** | **1 008** | **91 753** | **(219)** | **(71 853)** | **74** | **(12 785)** | **7 979** |
| Restatements related to IFRS 16 1st application | | | | | (81) | | | (81) |
| **Restated equity as of** | **01/01/2019** | **1 008** | **91 753** | **(219)** | **(71 934)** | **74** | **(12 785)** | **7 898** |
| Allocation of the profit / (loss) | | | | | (12 785) | | 12 785 | |
| Capital transactions | | 214 | 6 503 | | 74 | | | 6 792 |
| Share-based payment transactions | | | | | 952 | | | 952 |
| Treasury shares transactions | | 1 | | 32 | (224) | | | (192) |
| Comprehensie income as of | 12/31/2019 | | | | (26) | 101 | (15 272) | (15 197) |
| **Equity as of** | **12/31/2019** | **1 223** | **98 257** | **(188)** | **(83 943)** | **176** | **(15 272)** | **253** |

**CASH-FLOW STATEMENTS**
(Amounts in thousands of euros)

| | Note | 12/31/2019 | 12/31/2018 (*) |
|---|---|---|---|
| **Cash flow from operating activities** | | | |
| Profit / (Loss) | | (15 272) | (12 785) |
| Elimination of amortization, depreciation and provisions | | 1 178 | 1 130 |
| Share-based payment transaction expense and revenue | **10** | 952 | 138 |
| Other items excluded from the auto-financing capacity | | 1 028 | 643 |
| *Revenue and expenses related to the discounting of repayable advances* | **11** | *657* | *67* |
| *Revenue and expenses related to the bonds* | **11** | *(268)* | *71* |
| *Net financial interests* | **11** | *601* | *481* |
| *Other non-cash items* | | *39* | *24* |
| Capital gain or loss from asset sales | | 8 | (0) |
| **Auto-financing capacity** | | **(12 105)** | **(10 874)** |
| | | | |
| Change in WCR related to business activities | | 1 834 | (26) |
| *Inventories & work in progress* | **6** | *(238)* | *(313)* |
| *Trade receivables* | **7** | *(783)* | *433* |
| *Other current assets* | **7** | *350* | *(557)* |
| *Trade payables* | **13** | *155* | *419* |
| *Other current liabilities* | **13** | *2 351* | *(8)* |
| **Net cash flows from operating activities (A)** | | **(10 272)** | **(10 900)** |
| | | | |
| **Cash flow from investing activities** | | | |
| Purchase of property, plant and equipment and intangible assets | **3/4** | (1 381) | (1 254) |
| Proceeds from sale of property, plant and equipment and intangible assets | | 0 | 1 |
| Change in loans and advances granted | | (40) | 7 |
| Other cash flows from investing operations | | 5 | |
| **Net cash flows from investing activities (B)** | | **(1 416)** | **(1 246)** |
| | | | |
| **Cash flow from financing activities** | | | |
| Proceeds from exercise of share options | **10** | | 3 804 |
| Proceeds from issue of shares | **10** | 6 792 | 10 |
| Cash received from new loans issuance | **11** | 11 500 | |
| Net reimbursments - IPF loan | **11** | (4 264) | |
| Fees on issuance and reimbursment of loans | **11** | (1 733) | |
| Reimbursment of debt on leases (IFRS 16) | **11** | (491) | |
| Other financial interests paid | **11** | (39) | (357) |
| Financing of Tax Research Credit | **11** | 1 442 | |
| Other cash flows from financing operations | | (170) | (158) |
| **Net cash flows from financing activities (C)** | | **13 036** | **3 299** |
| Net foreign exchange difference (D) | | 10 | 16 |
| **Change in cash (A) + (B) + (C) + (D)** | | **1 358** | **(8 830)** |
| | | | |
| Cash at the beginning of the period | **9** | 8 623 | 17 453 |
| Cash at the end of the period | **9** | 9 982 | 8 623 |
| | | | |
| **Change in cash** | | **1 359** | **(8 830)** |

(*) IFRS 16 has been applied using the simplified retrospective method, therefore the comparative period at December 31, 2018 has not been modified (see Note 1.1)

Mauna Kea Technologies, inventor of Cellvizio, a multidisciplinary confocal laser endomicroscopy platform using microprobes and needles, designs and sells medical devices specializing in endomicroscopy to eliminate diagnostic uncertainties in biopsy. Applications relate to the fields of gastroenterology, pulmonology and urology. A global player in real-time cellular diagnostics, the Company's prime objectives are to constantly improve the quality of care provided to patients and efficiency of healthcare professionals and systems.

The Company's flagship product, Cellvizio, has received clearance to sell for a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico.

A decision in France in 2019 by UNICAM provided for a procedural code for reimbursement of esophageal endoscopy with confocal laser-guided endomicroscopy biopsy.

**Highlights of the financial year**

Financial debt was restructured during the financial year.

The IPF Partners financing, issued in February 2017 and again in May 2019 totaling €9 million, was fully repaid on June 28, 2019 for €10.7 million including early repayment fees.

Financing of €22.5 million was contracted on June 20, 2019 with the European Investment Bank (EIB). The first instalment of this financing, for €11.5 million, repayable in full after 5 years, was received on July 3, 2019. This loan, together with 1,450,000 warrants (BSA) repayable in shares or cash, is intended to finance 50% of future research expenses.

A €7.5 million capital increase reserved for Johnson & Johnson Innovation Inc. through the issue of 5,357,142 new ordinary shares for a unit subscription price of €1.40, raises this company's stake in Mauna Kea Technologies to 17.5% at the end of 2019.
This capital increase is intended to finance current operations, in particular in the fields of clinical studies, development activities, and sales and marketing efforts in the United States.

Furthermore, Research Tax Credit receivables in respect of the 2017 and 2018 and part of the 2019 financial years were sold in May and October 2019 for €2 million and €0.5 million respectively.

**Note 1: Accounting principles**

1.1 Accounting principles applied by the Group

The financial statements are presented in thousands of euros. Rounding may in some cases cause insignificant variances in totals.

They were approved by the Board of Directors at its meeting of April 27, 2020. These financial statements will be definitive only after their approval by the Annual General Meeting.

The financial statements are prepared on the basis of historical cost with the exception of financial assets, which are measured at their fair value. The preparation of the financial statements according to IFRS principles requires that estimates be made and assumptions formulated which impact the amounts and information provided therein with respect to measuring the cost of share-based payments, measuring the value of the research tax credit, and measuring value in use with regard to impairment testing. These assumptions and estimates were made on the basis of information or positions at the date the financial statements were prepared and may differ from actual results. As applicable, a sensitivity analysis may be implemented if this variation is significant.

The going concern assumption was adopted by the Board of Directors taking into account the following elements:

- Cash available at December 31, 2019 stood at €10 million;
- The drawdown of the second instalment of €6 million provided for under the contract signed with the EIB in 2019 following the withdrawal by the EIB of the sales condition associated with that drawdown;
- The payment on April 20 of a U.S. paycheck protection loan of approximately €0.6 million to MKT Inc.;
- The granting of a repayable advance and a grant for PERSEE project of €0.5 million in 2020;
- The receipt of the balance of the research tax credit for 2019 and the pre-financing of the research tax credit for 2020 for an amount of €0.8 million;
- Sales outlook taking into account the impact of the Covid-19 crisis.

In this context, the Group considers that it is in a position to meet its commitments until December 31, 2020.

This financial information was prepared on the basis of the principles underlying all the standards and interpretations adopted by the European Union whose application is mandatory at December 31, 2019. These standards and interpretations are available on the European Commission website:
https://ec.europa.eu/info/law/international-accounting-standards-regulation-ec-no-1606-2002/amending-and-supplementary-acts/acts-adopted-basis-regulatory-procedure-scrutiny-rps_fr

The Group applied IFRS 16 for the first time as of the financial year beginning on January 1, 2019, which relates to operating leases with a term of more than twelve months and whose assets have a unit value of more than USD 5,000.

This standard, which is mandatory from 2019, has led to an increase in debt and assets (right of use of assets) of €1.4 million and mainly concerns real estate leases in France and the USA as well as motor vehicle leases.

The impact of the first-time application of this standard on the financial statements is shown in the following tables:

**Impact of 1st application of IFRS 16 on the consolidated statement of financial position**

| | January 1st, 2019 | | |
|---|---|---|---|
| (in thousands of euros) | **Without IFRS 16** | **Impact of IFRS 16** | **With IFRS 16** |
| **ASSETS** | | | |
| Tangible assets | 1 985 | 1 432 | 3 416 |
| **Total non-current assets** | **3 956** | **1 432** | **5 388** |
| **TOTAL ASSETS** | **19 762** | **1 432** | **21 193** |
| | | | |
| **LIABILITIES** | | | |
| Long-term debt | 6 457 | 1 022 | 7 479 |
| **Total non-current liabilities** | **6 879** | **1 022** | **7 901** |
| Short-term debt | 600 | 491 | 1 091 |
| **Total current liabilities** | **4 904** | **491** | **5 395** |
| | | | |
| Reserves | -72 073 | -81 | -72 153 |
| **Total Equity** | **7 979** | **-81** | **7 898** |
| | | | |
| **TOTAL LIABILITIES AND EQUITY** | **19 762** | **1 432** | **21 193** |

## Impact on profit/(loss)

| | As of December 31st, 2019 | | |
|---|---|---|---|
| (in thousands of euros) | **Without IFRS 16** | **Impact of IFRS 16** | **With IFRS 16** |
| **Current operating profit** | **-13 309** | **74** | **-13 235** |
| Financial expenses | -3 569 | -49 | -3 618 |
| **Net result** | **-15 970** | **25** | **-15 945** |

## Impact on the cash flow statement

| | As of December 31st, 2019 | | |
|---|---|---|---|
| (in thousands of euros) | **Without IFRS 16** | **Impact of IFRS 16** | **With IFRS 16** |
| **Net result of consolidated companies** | **-15 970** | **25** | **-15 945** |
| Amortization and depreciation | 956 | 430 | 1 385 |
| Financial expenses | 552 | 49 | 601 |
| Change in WCR | -514 | 31 | -483 |
| **Net cash flows from operating activities** | **-12 275** | **535** | **-11 740** |
| Rent paid on the period | 0,00 | -491 | -491 |
| **Net cash flows from financing activities** | **13 554** | **-491** | **13 063** |
| **(Decrease)/Increase of treasury** | **-127** | **44** | **-83** |

Reconciliation between rental commitments at December 31, 2018 and IFRS 16 rental liabilities at January 1, 2019

**Reconciliation between commitments given for operating leases as of December 31st, 2018 and the lease liability as of January 1st, 2019**

(in thousands of euros)

| | |
|---|---|
| Commitments given for operating leases as of December 31st, 2018 | 811 |
| Commitment discounted using the incremental borrowing rate as of 1st application date | 747 |
| (-) Contracts with term below 12 months and/or low value | -29 |
| (+) On-going contracts identified under IFRS 16 (1) | 795 |
| (+) Adjustment related to variation of index or rate | |
| (+) Modification of contracts with effect as of January 1st, 2019 | |
| **Lease liability as of January 1st, 2019** | 1 513 |
| Including : | |
| Current liability | 491 |
| Non-current liability | 1 022 |

(1) This amount is composed of 767 K€ for difference of treatment for the renewal options between IFRS 16 and commitment as of December 31st, 2018 and of 28 K€ for commitments not recognized at the same date and considered as non material.

The other standards adopted by the European Union, whose adoption is mandatory as of January 1, 2019 and which had no impact on the financial statements at the end of 2019, are:

- IFRIC 23 – "Uncertainties regarding tax treatment"
- Amendments to IFRS 9: "Early redemption characteristics with negative remuneration".
- Amendments to IAS 19 – "Employee benefits": amendment, reduction or liquidation of a plan
- Annual improvements (2015-2017) to IFRS

Furthermore, the Group has not opted for the early application of the standards and interpretations published by IASB but not yet adopted by the European Union as of December 31, 2019, in particular:

- Amendment to IAS 1 "Presentation of financial statements"
- Amendment to IAS 8 "Accounting policies, changes in accounting estimates and errors"
- Amendments to IFRS 10 and IAS 28 "Sale or contribution of assets between an investor and its associate or joint venture"
- Amendments to IAS 40 "Transfers of investment property"
- IFRS 17 "Insurance contracts"

1.2 Consolidation methods

Subsidiaries are all the entities over which the Company exercises control with regard to financial and operating policy and of which it generally holds more than half of the voting rights. The subsidiaries are consolidated by the full consolidation method beginning on the date on which the Company acquires the control of them. They are deconsolidated from the date on which control cease to be exercised.

At December 31, 2019, the group owns a single US subsidiary Mauna Kea Technologies Inc.

The intra-group transactions and balances are eliminated. The accounting methods of the subsidiaries have been aligned with those of the Company.

1.3 Net investments abroad

In accordance with IAS 21.15, foreign exchange gains and losses on long-term receivables in US dollars owed by a subsidiary to the Company are recognized in equity. Indeed, these accounts receivables are considered as net investments in currencies within consolidated foreign subsidiaries, considering the unforeseeable nature of the payment of these receivables.

1.4 Intangible assets

In accordance with IAS 38, intangible assets acquired are recognized as assets in the balance sheet at their acquisition or production cost. The subsidies received and related the capitalized expenses are recognized as a reduction of cost.

Research and development expenses

The research expenses are consistently recognized as expenses.

In accordance with IAS 38, development costs are recognized as intangible assets only if all the following criteria are met:

(a) the Company has established the technical feasibility necessary for the completion of the development project,
(b) the Company intends to complete the project and use it,
(c) the Company is able to use the intangible asset,
(d) the Company is able to demonstrate the likelihood of future economic benefits from the asset,
(e) the Company has the technical, financial and other resources necessary to complete the project,
(f) the Company is able to reliably measure the costs of developing the asset.

In application of this standard, the Company recognized all its R&D costs as expenses, until the first prototypes of Cellvizio were refined.
Development expenses related to finalizing new products were recognized as assets as long as they met the criteria of IAS 38. Expenses related to research and the improvements of existing products remain as expenses for the financial year.

Development costs carried as assets are amortized on a straight-line basis over seven years or five years for Cellvizio's second generation development costs, i.e. their useful life. Useful life is incorporated into the current period until the asset becomes obsolete.

Patents

Patent filing costs incurred by Mauna Kea Technologies until the patents are obtained are recognized as intangible assets in line with the criteria for capitalizing development costs stipulated by IAS 38.

They are amortized on the basis of the straight line method over the term of protection granted.

Software packages

Costs relating to the acquisition of licenses for software packages are recognized as assets on the basis of the costs incurred to acquire and implement them.

They are amortized using the straight-line method over a period of one to three years.

1.5 Property, plant, and equipment

Property, plant and equipment subject to a lease of more than twelve months and covering assets whose individual replacement value as new is more than USD 5,000 have, since January 1, 2019, been recognized as an asset representing the right of use of the leased asset. The initial valuation of the asset is estimated using the amortized cost model and depreciated over the shorter of the lease term or the term of the right of use, in accordance with the requirements of IFRS 16.

Acquired property, plant, and equipment is recognized at acquisition or production cost. The renovations and major improvements are capitalized, and the repair and maintenance expenses and the costs of the other renovation work are expensed as incurred. The subsidies received and related the capitalized expenses are recognized as a reduction of cost.

Property, plant, and equipment are depreciated on the basis of the straight-line method over the estimated lifetime of the property. The fixtures of property rented are depreciated over the term of their own lifetime or over the term of the rental agreement, whichever is shorter.

Cellvizios entrusted to hospitals under partnership agreements (reference centers) and Cellvizios made available under a consignment contract are recorded under capital assets.

Depreciation and amortization periods are as follows:

Fixtures and fittings.....7 years
Research and development tools.....2 to 5 years
Production tools.....3 to 7 years
Cellvizio granted to reference centers, lent or consigned.....5 years
Research equipment and technical facilities.....7 years
Office and computer equipment, furniture.....5 years
Computer equipment .....3 years

1.6. Recoverable amount of non-current property, plant and equipment and intangible assets

Intangible assets and property, plant, and equipment are tested for impairment if the recovery of their book value is uncertain. With respect to intangible assets in progress, even in the absence of indicators of impairment, an impairment test is conducted annually.

An impairment loss is recognized to the extent that the carrying amount exceeds the recoverable value of the asset. The recoverable value of an asset corresponds to its fair value minus the costs of sale or its value in use, if the latter is higher. With respect to the Company's intangible assets, there are no market data that allow the net fair value of the costs of sale to be determined other than by an estimation of future cash flows. Consequently, the recoverable amount is essentially equal to the value in use.

The value in use is determined each year, in accordance with IAS 36: it corresponds to the discounted value of estimated future cash flows expected from the continued use of the assets and their disposal at the end of the intended use by the business. It does not take into account the impact of the financial structure, tax effects, or restructuring efforts not undertaken.

The recoverable amount must be estimated for each individual asset. If this is not possible, IAS 36 requires a company to determine the recoverable amount of the cash-generating unit (CGU) to which the asset belongs. Only one cash-generating unit has been defined at Group level. It is therefore at Group level that this impairment test was performed.

This value is based on the discounted cash flow method over a period of 5 years and using a terminal value calculated on the basis of an updated standard flow with a growth of 2%.

The future cash flows over the period 2020 to 2024 are based on the following assumptions:

- An average sales growth rate broken down by geographic area and by distribution model (pay-per-use, direct sales of systems, sales to distributors)

- A constant margin rate taking into account the cost of products sold depending on the type and generation of the products

- A constant distribution of expenses by type (R & D, Sales & Marketing and General Expenses)

- Investments (including systems made available through the pay-per-use program in the United States)

1.7 Financial assets

The Company's financial assets include loans and receivables, and the cash and cash equivalents.

The measurement and recognition of financial assets and liabilities are defined by IFRS 9 – Financial Instruments.

Loans and receivables

This category includes trade receivables, the other loans and receivables, and deposits and guarantees, which are classified under non-current financial assets on the balance sheet.

These instruments are initially recognized at their fair value and then at amortized cost using the effective interest rate (EIR) method. Short-term receivables without a nominal interest rate are measured at the amount of the original invoice unless the application of an implicit interest rate has a material impact. For variable-rate loans and receivables, a periodic re-estimation of cash flow variations, in order to translate changes in market interest rates, modifies the effective interest rate and consequently the valuation of the loan or receivable.

The Company analyzes each of its trade receivables past due to determine whether an impairment loss should be recognized.

Loans and receivables are monitored for any objective indication of impairment. A financial asset is impaired if its book value is greater than its recoverable amount as estimated during impairment tests. The impairment is recognized in the income statement.

Assets at fair value through profit or loss

Assets considered to be held for sale include assets that the Company intends to resell in the near future in order to realize a capital gain and that are part of a portfolio of financial instruments managed together customarily sold in the short term.

1.8 Inventories and work in progress

The inventories are valued at their cost or at their net realizable value (NRV), if the latter is lower. In the latter case, a corresponding impairment loss is recognized in profit or loss.

Inventories of raw materials are valued according to the weighted average cost method.

Inventories of semi-finished and finished products are valued at the standard cost taking into account the cost of materials used, labor costs and a share of overheads.

1.9 Cash and cash equivalents

Cash equivalents are held to meet short-term cash commitments rather than for investment or other purposes. They are readily convertible, into a known amount of cash, and are subject to a negligible risk of change in value. The cash and cash equivalents are constituted by liquid assets that are available immediately, long-term investments that can be liquidated immediately, and short-term investment securities. They are evaluated on the basis of the IFRS 9 according to the categories they belong to.

The short-term investment securities are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. They are measured at fair value, and changes in value are recorded in the financial gains or losses

1.10 Share capital

Costs of share capital transactions that are directly attributable to the issue of new shares or options are recognized in equity as a deduction from the proceeds of the issue, net of tax.

1.11 Liquidity contract

Following its listing on the NYSE Euronext Paris regulated market, the Company signed a liquidity contract with a specialized institution in order to limit the intraday volatility of the Mauna Kea Technologies stock.

The portion of the contract that is invested in own shares of the Company by this service provider is posted to the accounts as a deduction from the consolidated shareholders' equity of the Company at the end of each financial year. The balance of “liquidity” is recorded as current financial assets.

1.12: Share-based payments

Since its formation, the Company has established several plans for compensation paid in equity instruments in the form of BSPCEs (special stock warrants with tax benefits) granted to employees and/or executives, stock warrants granted to non-employee members of the Board of Directors or the Supervisory Board, stock options granted to employees of the subsidiary Mauna Kea Technologies Inc., and bonus preferred shares awarded to employees and/or executives.

In accordance with IFRS 2, the cost of transactions settled in equity instruments is recorded as an expense with a counterpart increase in equity over the vesting period.

The Company has applied IFRS 2 to all equity instruments granted since 2002 to employees, members of the Board of Directors or the Supervisory Board, natural persons, or entities.

The fair value of stock options or performance shares granted to employees is determined using the Black- Scholes option valuation model. The same applies to options granted to other natural persons who provide similar services, the market value of the latter not being ascertainable.

The determination of the fair value of the converted instruments includes the vesting conditions described in Note 17: Share-based payments. The other factors taken into consideration are also presented in Note 17: Share-based payments.

1.13 Measurement and recognition of financial liabilities

Financial liabilities at the amortized cost

Borrowings and other financial liabilities are valuated initially at their fair value and then at amortized cost using the EIR method.

Transaction costs that are directly attributable to the acquisition or issue of a financial liability are deducted from that financial liability. These expenses are then amortized actuarially over the lifetime of the liability, on the basis of the EIR.

The EIR is the rate at which expected future cash outflows are equal to the net present carrying amount of the financial liability from which their amortized cost is deducted.

As of December 31, 2019, the Group pre-financed the Research Tax Credit receivable for financial years 2018 and 2019 with a financial institution. According to the decision tree of IAS 39 regarding the derecognition of financial assets, it was concluded that the Group had not transferred substantially all of the risks and rewards inherent in the transferred Research Tax Credit receivable. Therefore this receivable has not been derecognized, and the funds received from the receivable sale are recognized in current loans and borrowings.

Liabilities at fair value through profit and loss

The liabilities at fair value through profit and loss are measured at their fair value.

In accordance with the provisions of IFRS 9 and the clarifications made in autumn 2017 by the IFRS Interpretation Committee on the treatment of debt changes deemed not to be derecognizable, the Group immediately restates in the income statement the effect of changes in contractual borrowing conditions. The effective interest rate is thus maintained on the residual maturity of the debt.

As part of the financing with the European Investment Bank (EIB), the Group issued share warrants (BSA). This issuance has been analyzed according to IFRS 9 criteria. Because of the put option and the variable nature of the number of shares to which the warrants (BSA) will give entitlement, it is recognized as a derivative instrument and measured at fair value on the grant date. It is then remeasured at each reporting date with a corresponding adjustment in profit/(loss)

1.14 Conditional advances

The Company receives a certain number of forms of assistance, in the form of subsidies or conditional advances. The details concerning this assistance are provided in Note 11: Borrowings and financial debts.

A conditional non-repayable loan is treated as a public subsidy if there is reasonable assurance that the Company will fulfill the conditions under which the loan need not be repaid. If the contrary is the case, it is classified under debts.

The unpaid interest benefit resulting from an interest-free repayable loan is considered a subsidy. It is calculated by applying a discount rate equal to the contractual rate, if known, or to 10-year OAT yields (French Treasury bonds).

1.15 Provisions

Provisions for risks and expenses

Provisions for risks and expenses correspond to commitments arising from litigation and miscellaneous risks, whose timing and amount are uncertain, and which the Group may face in the course of its business.

A provision is recognized when there is a legal or implicit obligation to a third party resulting from a past event which is likely or certain to cause an outflow of resources to that third party, without the expectation of at least equal compensation from it, and for which the future outflows of liquid assets can be estimated reliably.

An amount recognized as a provision is the best estimate of the expenditure necessary to settle the obligation, which is discounted if necessary on the closing date.

Retirement pension and post-employment benefits

The employees of the Company receive the retirement benefits stipulated by law in France:

- retirement benefits paid by the Company to employees upon their retirement (defined benefit plans);
- payment of pension benefits by Social Security agencies and financed by contributions made by employers and employees (defined contribution plans).

For the defined benefit plans, the costs of the retirement benefits are estimated by using the projected credit unit method. According to this method, the cost of the retirement pensions is recognized in the income statement in such a manner as to distribute it uniformly over the term of the services of the employees. The retirement benefits commitments are valuated at the current value of the future payments estimated using the market rate based on the long-term obligations of the first-category companies with a term that corresponds to that estimated for the plan.

The Company relies on actuaries qualified to conduct an annual review of the valuation of these plans.

In accordance with IAS 19 “Defined Benefit Plans: Employee Contributions”, service costs and net interest are recorded under operating profit (loss) and other remeasurements are recorded under other comprehensive income.

The Company's payments for the defined contribution plans are recognized as expenses on the income statement of the period with which they are associated.

1.16 Revenue from ordinary activities

The Group recognizes revenue from ordinary activities according to IFRS 15.

Revenue from ordinary activities is measured as the fair value of the consideration received or receivable for the sale of goods in the ordinary course of the Company's business. Revenue from ordinary activities is presented net of value-added tax, product returns, rebates and discounts, and intragroup sales.

Revenue is recorded when the transfer of goods or services promised to a customer is completed for the amount that reflects the payment that the entity expects to receive as consideration for those goods or services. Regarding the sale of products, revenue is recognized either at the products availability or delivery according to the order's conditions. In the case of a contract to supply our systems, Cellvizio remains an asset of the Company and the revenue is recognized under sales of consumables or services performed by healthcare professionals.

1.17 Other income

Subsidies

Since it was created, and because of its innovative nature, the Company has received financial assistance or subsidies from the French government or local public authorities intended to fund its operations or recruit specific personnel.

Subsidies are recorded when there is a reasonable assurance that:
- the Company will comply with the conditions attached to the subsidies; and
- the subsidies will be received.

A public subsidy to be received as compensation for either costs or losses already incurred, or as immediate financial support without associated future costs, is recorded under "Other income" for the year in which the loan is granted. Otherwise, it is recorded under "Other income" for the year in which the corresponding charges or expenses are recorded.

Research Tax Credit

Research tax credits are granted to companies by the French government in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the financial year in which the expenditures were made and the next three financial years, or, as applicable, be reimbursed for the excess portion.

The part of the tax credit used to finance research costs is recognized under "Other income" for the year in which the costs are incurred. The part used to finance eligible development costs is deducted from costs recorded under assets.

1.18 Other operating income and expenses

This concerns unusual income or expenses of a significant amount and limited in number and frequency that the Company presents as a separate item on its income statement in order to facilitate understanding of its recurring operational performance and provide useful information for a forward-looking analysis of results.

1.19 Cost of sales

Cost of sales is made up of raw material consumption, labor costs, depreciation and amortization, inventory allowances, and overheads relating to production.

1.20 Leases

The Group applied IFRS 16 "Leases" from January 1, 2019 by using the simplified retrospective method. Rights of use from operating leases whose term is longer than 12 months and with a replacement value as new of more than USD 5,000 for each of the leased assets have been recognized as assets offset by a lease liability corresponding to the discounted value of the rent to be paid over a reasonably certain lease period. These contracts mainly include the leases for the Company's head office in France and the Boston offices as well as motor vehicle leases.

The discount rate used at the transition date corresponds to the implicit rate of the lease if existing or the incremental borrowing rate that would be obtained for a loan contracted for an almost identical period to the remaining term of the ongoing leases as of January 1, 2019. For future leases, the same method will be used if an implicit rate is not available. The weighted average marginal borrowing rate of the lessee, applied to lease liabilities as of January 1, 2019, has been estimated at 2% for the lease of the Paris offices and for

the other leases held by Mauna Kea Technologies SA. A rate of 12% was used for the lease of the American premises corresponding to the implicit interest rate provided for in the contract.

The rights of use were measured as if IFRS 16 had been in force since the lease agreements were signed. The equity at January 1, 2019 was therefore impacted by -€81 thousand, which the Company considers immaterial. The application of IFRS 16 did not have an impact the Group's cash and cash equivalents.

The Group applied the following simplification measures:

- Use of a single discount rate for a portfolio of leases with reasonably similar characteristics;
- Use of previous valuations to determine whether the leases involve a financial outlay;
- Recognition of rental expenses from short-term leases (those with terms less than or equal to 12 months which do not include purchase options and/or leases concerning low value assets);
- Use of knowledge acquired retrospectively to calculate, for example, the term of the lease when it includes extension or termination options.

1.21 Taxes

The deferred income taxes are recognized on the basis of the broad conception and on the basis of the liability method, for all the temporary differences between the value for tax purposes and the stated book value of the assets and liabilities that appear within the financial statements. The primary temporary differences are related to the tax losses that can be carried forward or backward. The tax rates stipulated by law at the closing date are used to determine deferred taxes.

Deferred tax assets are only recognized to the extent that probable future profits will be sufficient to absorb the losses carried forward. In view of its stage of development, the Company does not recognize net deferred tax assets.

1.22 Segment information

The Company has not at this date identified separate operating segments. It conducts its business in a single operating segment: endomicroscopy.

1.23 Other comprehensive income

The revenue and expense items for the period recognized directly in equity are presented, as applicable, under the rubric “Other comprehensive income”. These are principally:

- EUR/USD exchange rate differences relating to the subsidiary Mauna Kea Technologies, Inc.;
- changes in pension plan provisions arising from changes in actuarial assumptions.

1.24 Significant accounting estimates and judgments

Estimates and judgments made by management when applying the accounting policies described above are based on historical information and other factors, notably the anticipation of future events judged to be reasonable in light of circumstances. These estimates and judgments are primarily the following:

*Valuation of stock warrants, stock options and preferred stock*

The fair value of stock warrants and stock options granted to employees or service providers is measured on the basis of actuarial models. These models rest on certain calculation assumptions such as the expected volatility of the security.

*Valuation of the Research Tax Credit*

Income relating to the research tax credit is measured on the basis of methods detailed in Note 1.17 “Other income - Research Tax Credits”.

*Valuation of the long-term intangible assets*

The value in use of intangible assets is measured on the basis of assumed sales growth and a discount rate that reflect the best estimates of management.

1.25 Subsequent events

The balance sheet and the income statement of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that exist as of the closing date. Adjustments are made until the date on which the financial statements are approved by the Board of Directors.

Events subsequent to the closing date that did not result in adjustments are presented in Note 25 "Subsequent events".

**Note 2: Company and scope**

Founded in May 2000, Mauna Kea Technologies SA ("the Company") develops and markets medical devices, particularly optical instruments for medical imaging.

As part of its development in the United States, the Company created Mauna Kea Technologies Inc. on January 3, 2005.

| | 12/31/19 | | 12/31/18 | | Consolidation method |
|---|---|---|---|---|---|
| Entities | % of interests | % of control | % of interest | % of control | |
| Mauna Kea Technologies SA (1) | 100% | 100% | 100% | 100% | Full consolidation |
| Mauna Kea Technologies Inc | 100% | 100% | 100% | 100% | Full consolidation |

(1) Group's parent company

No change in scope took place during the period.

**Note 3: Intangible assets**

The changes in intangible assets break down as follows:

**INTANGIBLE ASSETS**
(Amounts in thousands of euros)

| | 12/31/2017 | Increase | Decrease | Reclassification | 12/31/2018 |
|---|---|---|---|---|---|
| Development costs | 3 623 | | | | 3 623 |
| Patents, licenses and trademarks | 1 674 | 17 | | 4 | 1 695 |
| Software packages | 664 | 38 | | 210 | 913 |
| Patents, licenses and trademarks in progress | 546 | 46 | | (4) | 588 |
| **Total gross of intangible assets** | **6 508** | **101** | | **210** | **6 819** |
| Amort. / dep. of development costs | (3 135) | (377) | | | (3 512) |
| Amort. / dep. of patents, licenses and trademarks | (789) | (122) | | | (912) |
| Amort. / dep. of software packages | (483) | (74) | | | (558) |
| **Total amort. / dep. of Intangible assets** | **(4 408)** | **(573)** | | | **(4 981)** |
| **Total net of Intangible assets** | **2 100** | **(472)** | | **210** | **1 838** |

**INTANGIBLE ASSETS**
(Amounts in thousands of euros)

| | 12/31/2018 | Increase | Decrease | Reclassification | 12/31/2019 |
|---|---|---|---|---|---|
| Development costs | 3 623 | 838 | | | 4 461 |
| Patents, licenses and trademarks | 1 695 | | | 96 | 1 791 |
| Software packages | 913 | 12 | | | 924 |
| Patents, licenses and trademarks in progress | 588 | 6 | | (96) | 498 |
| **Total gross of intangible assets** | **6 819** | **855** | | | **7 675** |
| Amort. / dep. of development costs | (3 512) | (109) | | | (3 621) |
| Amort. / dep. of patents, licenses and trademarks | (912) | (138) | | | (1 050) |
| Amort. / dep. of software packages | (558) | (103) | | | (661) |
| **Total amort. / dep. of Intangible assets** | **(4 981)** | **(350)** | | | **(5 332)** |
| **Total net of Intangible assets** | **1 838** | **505** | | | **2 343** |

The development costs of the Gen III system, currently in the prototype phase, were capitalized for the first time in 2019, for €838 thousand at the end of 2019. Since March 2019, these costs have fulfilled the capitalization criteria pursuant to IAS 38:

- the technical feasibility of the intangible asset for use or sale
- the Group's intention to complete the asset and its ability to use or sell it
- expected future economic benefits from the asset

- available resources enabling the development of the system to be completed
- ability to reliably measure the costs of developing the asset

Amortization related to development costs for the second generation of Cellvizio amounted to €109 thousand in 2019.

Patents in progress are subject to an annual impairment test as part of the impairment test at the CGU level.

The Company tests the effects of a change in the cost of equity assumptions: the variation of +1 and -1 point respectively varies the valuation of the CGU by -3% and +3%.

The Company tests the effects of a change in the assumptions of the growth rate to infinity: the variation of +0.5 point and -0.5 point respectively varies the valuation of the CGU by +2% and -1%.

The Company tests the effects of a change in the assumptions of the rate of achievement of the turnover: The sensitivity to -10 points and +10 points varies respectively the valuation of the CGU of -4% and +4%.

In view of these results and summing up all the impacts of negative assumptions, the company did not recognize any impairment.

**Note 4: Property, plant, and equipment**

The changes in property, plant and equipment break down as follows:

**PROPERTY, PLANT AND EQUIPMENT**
(Amounts in thousands of euros)

| | 12/31/2017 | Increase | Decrease / Scrapping | Exchange differences | Reclassification | 12/31/2018 |
|---|---|---|---|---|---|---|
| Industrial equipment | 2 061 | 880 | | 10 | 162 | 3 113 |
| Fixture in buildings | 51 | | | | | 51 |
| Other tangible assets | 1 601 | 273 | (1) | 8 | (382) | 1 500 |
| **Total gross of Property, plant and equipment** | **3 713** | **1 153** | **(1)** | **18** | **(220)** | **4 664** |
| Amort. / dep. of industrial equipment | (1 325) | (298) | | (9) | | (1 631) |
| Amort. / dep. of fixture in buildings | (49) | (1) | | | | (50) |
| Amort. / dep. of other tangible assets | (873) | (128) | | (6) | 9 | (998) |
| **Total amort. / dep. of Property, plant and equipment** | **(2 248)** | **(427)** | | **(15)** | **9** | **(2 680)** |
| **Total net of Property, plant and equipment** | **1 466** | **727** | **(1)** | **4** | **(210)** | **1 985** |

**PROPERTY, PLANT AND EQUIPMENT**
(Amounts in thousands of euros)

| | 12/31/2018 | IFRS 16 01/01/2019 | Increase | Decrease / Scrapping | Exchange differences | Reclassification | 12/31/2019 |
|---|---|---|---|---|---|---|---|
| Industrial equipment | 3 113 | | 467 | (50) | 3 | 60 | 3 595 |
| Fixture in buildings | 51 | | | | | | 51 |
| Other tangible assets | 1 500 | | 58 | (39) | 3 | (60) | 1 461 |
| **Total gross of Property, plant and equipment** | **4 664** | | **525** | **(89)** | **6** | | **5 107** |
| Amort. / dép. du matériel industriel | (1 631) | | (240) | 42 | (3) | (184) | (2 017) |
| Amort. / dep. of fixture in buildings | (50) | | (1) | | | | (51) |
| Amort. / dep. of other tangible assets | (998) | | (306) | 39 | (2) | 184 | (1 083) |
| **Total amort. / dep. of Property, plant and equipment** | **(2 680)** | | **(547)** | **80** | **(5)** | | **(3 151)** |
| **Total net of Property, plant and equipment** | **1 985** | | **(21)** | **(9)** | **1** | | **1 956** |
| | | | | | | | |
| Right of use | n/a | 4 230 | 369 | | | | 4 598 |
| Amort. / dep. of right of use | n/a | (2 798) | (430) | | | | (3 228) |
| **Total net of Right of use** | **n/a** | **1 432** | **(61)** | | | | **1 370** |

The application of IFRS 16 Leases had a net impact of €1,432 thousand on property, plant and equipment as of January 1, 2019. Depreciation recognized with respect to these assets represented €430 thousand for the 2019 financial year.

**Note 5: Non-current financial assets**

Non-current financial assets only comprised security deposits paid under operating leases.

**Note 6: Inventories and work in progress**

The inventories and work in progress break down as follows:

**INVENTORIES & WORK IN PROGRESS**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Inventories of raw materials | 1 212 | 1 041 |
| Inventories & work in progress of finished goods | 1 547 | 1 552 |
| **Total gross of inventories & work in progress** | **2 760** | **2 592** |
| Dep. of inventories of raw material | (79) | (53) |
| Dep. of inventories & work in progress of finished goods | (89) | (83) |
| **Total dep. of inventories & work in progress** | **(168)** | **(136)** |
| **Total net of inventories & work in progress** | **2 592** | **2 456** |

## Note 7: Trade receivables and other current assets

7.1 Trade receivables

**TRADE RECEIVABLES**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Trade receivables | 3 185 | 3 168 |
| Dep. of trade receivables | (740) | (1 525) |
| **Total net of trade receivables** | **2 444** | **1 643** |

The impairment of bad debts has been reversed up to the amount of the loss recorded, i.e. €936 thousand.

The allowance for doubtful receivables represents 23% of receivables in gross value compared to 48% in 2018.

The analysis of receivables as of December 31, 2019 break down as follows:

**DATE OF PAYMENT FOR TRADE RECEIVABLES**
(Amounts in thousands of euros)

| | Gross amount | Less than a year | Over a year |
|---|---|---|---|
| Trade receivables | 3 185 | 2 498 | 687 |
| Dep. of trade receivables | (740) | (281) | (459) |
| **Total net of trade receivables** | **2 444** | **2 217** | **228** |

7.2 Other current assets

The other current assets break down as follows:

**OTHER CURRENT ASSETS**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Staff and related accounts | 18 | 9 |
| Research Tax Credit | 1 894 | 2 186 |
| Other tax receivables | 305 | 309 |
| Other receivables | 355 | 193 |
| Prepaid expenses | 128 | 323 |
| **Total gross of other current assets** | **2 701** | **3 019** |
| Dep. of other current assets | | |
| **Total net of other current assets** | **2 701** | **3 019** |

The changes in the Research Tax Credit were as follows:

**CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE**
(Amounts in thousands of euros)

| | 12/31/2017 | Operating revenue | Payment received | Other | 12/31/2018 |
|---|---|---|---|---|---|
| Research Tax Credit | 1 917 | 1 097 | (828) | | 2 186 |

| | 12/31/2018 | Operating revenue | Payment received | Other | 12/31/2019 |
|---|---|---|---|---|---|
| Research Tax Credit | 2 186 | 997 | (1 055) | 10 | 2 138 |

Receivables at end-2019 represent the Research Tax Credits of 2018 and 2019.

Other tax receivables are related to deductible VAT and a requested VAT reimbursement totaling €236 thousand compared to €214 thousand at December 31, 2018.

Other receivables mainly included advances to suppliers amounting to €194 thousand compared to €122 thousand at December 31, 2018.

**Note 8: Current financial assets**

Current financial assets correspond to the cash balance of the securities account opened under the Company's liquidity contract held with Gilbert Dupont, which stood at €59 thousand at December 31, 2019 versus €64 thousand at December 31, 2018.

**Note 9: Cash and cash equivalents**

Cash and cash equivalents break down as follows:

**CASH AND CAHS EQUIVALENTS**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Short-term bank deposits | 9 982 | 8 623 |
| **Total of cash and cash equivalents** | **9 982** | **8 623** |

**Note 10: Share capital**

10.1 Issued capital

The share capital is set at one million two hundred twenty-two thousand eight hundred sixty-nine euros and sixty cents (€1,222,869.60). It is divided into 30,571,740 ordinary shares, fully subscribed and paid up, each with a par value of €0.04.

This figure does not include “Stock Warrants” (BSAs), founders' warrants (BSPCEs) or stock options granted to certain investors and natural persons, who may or may not be employees of the Company and free performance share units (PSUs).

The table below shows the history of the Company's share capital since December 31, 2019:

| Type of transaction | Issued capital (€K) | Share Premium (K Eur) | Number of shared comprising the issued capital |
|---|---|---|---|
| As of December 31, 2018 | 1,008 | 91,753 | 25,201 |
| Capital increase | 214 | 6,577 | 5,357 |
| Others | 1 | -74 | 13 |
| **Total as of December 31, 2019** | **1,223** | **98,257** | **30,571** |

The Company opened, in December 2017, an equity financing facility with Kepler Cheuvreux covering a maximum number of 2,250,000 shares available for subscription over a maximum period of 24 months, i.e. until December 1, 2019. No movement occurred in 2019.

By the decision of the Board of Directors on December 13, 2019 and the delegation granted by the Extraordinary General Meeting of October 5, 2018, the Company carried out a capital increase reserved for an investor through the issue of 5,357,142 shares with a nominal value of €0.04 and an issue price of €1.40. The share premium of €7,286 thousand was charged against the related issuance expenses, i.e. €756 thousand.

10.2 Share purchase warrants, stock options and preferred stock

Since its formation, the Company issued "Stock Warrants" (BSA), stock warrants for its employees ("BSPCE" and others) as well as stock options (SO) and free performance shares (PS), the changes since December 31, 2017 are represented below.

In 2018, the Company issued a new free preference share plan, the terms of which have been approved by the shareholders at the General Meeting of October 5, 2018, and new stock options and stock warrants plans.

The Company also opened, in December 2017, an equity financing facility with Kepler Cheuvreux covering a maximum number of 2,250,000 shares available for subscription over a maximum period of 24 months. The PACEO financing contract with Kepler Chevreux matured on December 4, and has not been renewed.

| Type | Date of granting | Exercise price | Outstanding at 12/31/2018 | Number of shares | Exercised | Cancelled | Outstanding at 12/31/2019 | Potential number of shares |
|---|---|---|---|---|---|---|---|---|
| Options granted before January 1st, 2019 | | | 2 237 059 | | - | 186 250 | 2 050 809 | 3 169 563 |
| SO | 07/02/2019 | 2,13 € | | 40 000 | | | 40 000 | 40 000 |
| SO | 19/05/2019 | 1,63 € | | 75 000 | | | 75 000 | 75 000 |
| BSA | 19/05/2019 | 1,84 € | | 170 000 | | | 170 000 | 170 000 |
| BSA BEI | 03/07/2019 | 1,89 € | | 1 450 000 | | | 1 450 000 | 1 450 000 |
| SO | 31/07/2019 | 1,68 € | | 127 500 | | | 127 500 | 127 500 |
| SO | 21/11/2019 | 0,86 € | | 55 000 | | | 55 000 | 55 000 |
| AP | 19/09/2019 | | | 150 | | 150 | - | 0 |
| AP | 20/11/2019 | | | 400 | | | 400 | 40 000 |
| | | | | 1 918 050 | 0 | 186 400 | 3 968 709 | 5 127 063 |

Following the consolidation of shares (four old shares for a new one) on May 25, 2011, four stock warrants, BSPCEs or stock options granted before that date are needed to subscribe for one new share. For warrants and options granted after that date, the ratio is one to one.

Starting from July 2014, the Company could no longer issue any new founders' warrants (BSPCE) plans, because it had exceeded the threshold of €150 million in market capitalization more than three years previously.

The terms and conditions for exercising preferred shares are described in the minutes of the Combined General Meetings of May 4, 2016 in resolution 19 and October 5, 2018 in resolutions 14 and 15. (https://www.maunakeatech.com)

10.3 Company's buyback of its own shares

The Extraordinary General Meeting of July 5, 2019, authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with the provisions of Article L. 225-209 et seq. of the French Commercial Code and in accordance with the General Regulation of the Autorité des Marchés Financiers (AMF) under the terms and conditions described below:

**Objectives of the share buyback program:**

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be concluded with an investment services provider, in accordance with a Code of Conduct approved by the AMF;
- to meet the obligations related to stock option, free share award, or employee savings plans, or other awards of shares to the employees and executives of the Company or the companies associated with it;
- to tender shares upon exercise of the rights attached to securities giving access to the share capital;
- to purchase shares to hold for their subsequent exchange or use as consideration in potential acquisitions; or
- conduct transactions for any purpose that may be authorized by law or any market practice that may be permitted by the market authorities.

**Maximum purchase price**: €30 per share excluding fees and commissions, with a total limit of €5,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the

calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

| | 2019 | | | | |
|---|---|---|---|---|---|
| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter | Total |
| Securities purchased | 188 271 | 160 904 | 387 291 | 359 400 | 1 095 866 |
| Price | 2,02 | 1,67 | 1,57 | 1,02 | |
| Total amount (in K€) | 381 | 268 | 608 | 367 | 1 624 |
| Securities sold | 173 316 | 169 636 | 366 040 | 389 907 | 1 098 899 |
| Price | 2,05 | 1,69 | 1,58 | 1,02 | |
| Total amount (in K€) | 356 | 286 | 579 | 399 | 1 620 |

At December 31, 2019, the Company held 35,786 Mauna Kea Technologies shares acquired at an average price of €1.37 equal to the realizable value on December 31, 2019.

**Note 11 : Borrowings and financial debts**

**CHANGES IN FINANCIAL DEBTS**

(Amounts in thousands of euros)

| | 12/31/2018 | Impact IFRS16 as of Jan 1st, 2019 | Receipt | Repayment | Capitalized interests | Other | 12/31/2019 |
|---|---|---|---|---|---|---|---|
| Repayable advance BPI ( ex Oseo) | 2 766 | | | | 657 | | 3 423 |
| Lease liability IFRS 16 | | 1 513 | | (491) | | 369 | 1 390 |
| Loan IPF | 4 274 | | 5 000 | (9 557) | 283 | | |
| Loan BEI | | | 11 500 | | 371 | (1 255) | 10 616 |
| Warrants BEI | | | | | | 522 | 522 |
| Research Tax Credit financing | | | 1 442 | | | | 1 442 |
| Other | 16 | | | | | 6 | 22 |
| **Total of financial debts** | **7 056** | **1 513** | **17 942** | **(10 048)** | **1 311** | **(358)** | **17 415** |

11.1 Advances from BPI (formerly OSEO)

On May 31, 2010, Mauna Kea Technologies obtained a repayable innovation loan in the amount of €3,416 thousand from OSEO as part of the PERSEE project. The PERSEE project aims to develop, validate and then market a device capable of improving diagnostic and preoperative assessment techniques for cancer patients. The first payments of the loan were as follows:

- first payment of €454 thousand on May 31, 2010;
- second payment of €1,138 thousand on December 21, 2011;
- third payment of €685 thousand on May 29, 2013;
- fourth payment of €626 thousand on December 22, 2016.

The fifth payment of €512 thousand has been delayed and should be received following the last key stage corresponding to the presentation of the clinical trial results. The advances granted carry interest at a rate of 2.45%.

The 2010 contract between Oseo, now BPI France, and the Company stipulates that the first repayment should take place once sales of €2,500 thousand on new products are reached.

The amount to repay, based on the new expected repayment schedule, will be €4,961 thousand, including capitalized expenses.

If no repayment occurs within 10 years of the first aid payment, Mauna Kea will be released from any obligation to pay a financial return.

In addition, if the cumulative sales amount is greater than €50,000 thousand, 2% of the sales generated must be paid over fifteen years.

In addition, the specific contract between BPI France (formerly Oseo) and Mauna Kea stipulates in Article 4.3 that in the event of a failure by the Company to comply with any of its obligations as listed in the contract, of any irregular tax and social security situation, of inaccurate or false declarations, of a contribution, merger, demerger, transfer of control or of assets of the Company, Mauna Kea SA must repay in advance the discounted value.

11.2 Loans

The loan contracted with IPF Partners in February 2017 and again in May 2019 totaling €9,000 thousand, was fully repaid on June 28, 2019 for €10,700 thousand including early repayment fees.

Following the €22,500 thousand financing agreement signed with the European Investment Bank (EIB) on June 20, 2019, the Company received the first instalment of €11,494 thousand net on July 3, 2019. The following instalements of €6,000 thousand and €5,000 thousand, respectively, will be available subject to achieving certain milestones.

The 1st instalment is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of 5 October 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants (BSA) may be exercised until the twentieth anniversary of their issuance, i.e. July 3, 2039.

This issuance has been analyzed according to IFRS 9 criteria. Because of the put option and the variable nature of the number of shares to which the warrants (BSA) will give entitlement, it is recognized as a derivative instrument and measured at fair value on the grant date (i.e. July 3 on the receipt of the first loan instalment). It is then remeasured at each reporting date with a corresponding adjustment in profit/(loss)

The financial instrument liability relating to the warrants (BSA) attached to the first tranche of the EIB loan was valued at €1,022 thousand on the grant date, using the following valuation assumptions:

- theoretical maturity: 20 years;
- probable maturity: 6 years;
- volatility: 50% in 6 years and 40% in 20 years;
- repo: 2.5% per annum;
- reference price: €1.98.
-

This derivative instrument of €1,022 thousand has been recognized as a financial liability.

The derivative has then been valued at €522 thousand at end-2019, using the following assumptions:

- theoretical maturity: 19.5 years;
- probable maturity: 5.5 years;
- volatility: 50% in 5.5 years and 40% in 19.5 years;
- repo: 2.5% per annum;
- reference price: €1.30.

The change in value between the grant date and December 31, 2019 was recognized in net financial income in the income statement.

The Effective Interest Rate (EIR) of the financial debt recognized in respect of the EIB loan is calculated by restating the value of the warrants at the grant date and the issue costs of the loan from the initial debt. At the grant date, it had been estimated at 7.45%.

11.3 Short-term loans and borrowings

Short-term loans and borrowings of €600 thousand at end-2018 relating to the IPF Partners loan have been fully repaid.

The Research Tax Credit receivables relating to financial years 2018 and part of 2019 were sold in 2019 for a value of €1,442 thousand.

11.4 Derivative financial instruments

As part of the financing with the European Investment Bank (EIB), the Group issued share warrants (BSA). This issuance has been analyzed according to IFRS 9 criteria. Because of the put option and the variable nature of the number of shares to which the warrants (BSA) will give entitlement, it is recognized as a derivative instrument and measured at fair value on the grant date (i.e. July 3 on the receipt of the first loan instalment). It is then remeasured at each reporting date with a corresponding adjustment in profit/(loss)

As of December 31, 2019, the fair value of the EIB warrants was €522 thousand (see Note 11.2 Loans).

11.5 Maturities of financial liabilities

The maturities of financial liabilities as of December 31, 2019 break down as follows:

**REPAYMENT TERMS OF FINANCIAL LIABILITIES**
(Amounts in thousands of euros)

| | Gross amount | Less than one year | One to three years | Three to five years | More than five years |
|---|---|---|---|---|---|
| Long-term loans and borrowings | 15 499 | | 704 | 11 602 | 3 193 |
| Short-term loans and borrowings | 1 916 | 1 916 | | | |
| Trade payables | 2 275 | 2 275 | | | |
| Other current liabilities | 3 380 | 3 380 | | | |
| **Total of financial liabilities** | **23 070** | **7 571** | **704** | **11 602** | **3 193** |

The maturities of long-term loans and borrowings relating to repayable advances are determined on the basis of estimates of expected repayments at December 31, 2019.

**Note 12: Non-current provisions**

Non-current provisions break down as follows:

| | 12/31/2017 | Allowance | Unused reversals | Used reversals | Others | 12/31/2018 |
|---|---|---|---|---|---|---|
| Pension plan provision | 183 | 16 | (26) | | 7 | 180 |
| Provision for personnel dispute | 28 | 57 | | | | 85 |
| Provision for software upgrade | 15 | | | | | 15 |
| Other provisions for expenses | 58 | 84 | | | | 142 |
| **Total of non-current provisions** | **283** | **158** | **(26)** | | **7** | **422** |

**NON-CURRENT PROVISIONS**
(Amounts in thousands of euros)

| | 12/31/2018 | Allowance | Unused | Used | Others | 12/31/2019 |
|---|---|---|---|---|---|---|
| Pension plan provision | 180 | 32 | (4) | | 26 | 234 |
| Provision for personnel dispute | 85 | | | (20) | | 65 |
| Provision for software upgrade | 15 | | (15) | | | |
| Other provisions for expenses | 142 | | (142) | | | |
| **Total of non-current provisions** | **422** | **32** | **(161)** | **(20)** | | **299** |

12.1 Retirement commitments

For estimated retirement commitments, the following assumptions were used for all categories of employees (employees, ETAM [Employees, Technicians, and Supervisors], and managers):

**PENSION PLAN PROVISION**

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| % social security expenses | 47% | 48% |
| Salary increases | 2% | 2% |
| Discount rate | 1,17% | 1,97% |

- retirement age: 65;
- terms of retirement: voluntary retirement;
- mortality table: INSEE 2018;
- collective agreement: metal industries;
- turnover: high and digressive based on age (24% in 2019).

The Company does not finance its pension plan provision. No retirements took place over the last two financial years.

The discount rate benchmark is the iBoxx Corporate AA10+.

12.2 Provisions for labor disputes

This provision covers personnel disputes at the end of December 2019.

**Note 13: Trade payables and other current liabilities**

No discounts were made on trade payables and other current liabilities because they matured within one year at the end of each financial year in question.

13.1 Trade payables

Trade payables break down as follows:

**TRADE PAYABLES**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Trade payables | 2 275 | 2 087 |

12.2 Other current liabilities

Other current liabilities break down as follows:

**OTHER CURRENT LIABILITIES**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Tax payables | 113 | 107 |
| Satff and social security payables | 2 514 | 1 554 |
| Deferred revenue | 752 | 555 |
| **Total of other current liabilities** | **3 380** | **2 216** |

Tax liabilities mainly concern payroll taxes, sales tax and value added tax.

Payroll-related liabilities represent provisions for paid leave, provisions for bonuses and commissions and social security contributions

Deferred revenues mainly comprise the deferred portion of training and equipment installation under IFRS 15.

**Note 14: Financial instruments on the balance sheet**

**FINANCIAL INSTRUMENTS ON BALANCE SHEET AND THEIR IMPACT ON THE PROFIT (OR LOSS)**
(Amounts in thousands of euros)

| As of December 31st, 2019 | Value on the Balance sheet | Fair value through profit or loss | Fair value through equity | Loans and receivables | Debt at amortized cost |
|---|---|---|---|---|---|
| **Assets** | | | | | |
| Non-current financial assets | 173 | | | 173 | |
| Trade receivables | 2 444 | | | 2 444 | |
| Other current assets (1) | 2 701 | | | 2 701 | |
| Current financial assets | 59 | | | 59 | |
| Cash | 9 982 | 9 982 | | | |
| **Total of assets** | **15 360** | **9 982** | | **5 378** | |
| **Liabilities** | | | | | |
| Long-term loans and borrowings | 15 499 | 522 | | | 14 977 |
| Short-term loans and borrowings | 1 916 | | | | 1 916 |
| Trade payables | 2 275 | | | | 2 275 |
| Other current liabilties (1) | 3 380 | | | | 3 380 |
| **Total of liabilties** | **23 070** | **522** | **0** | **0** | **22 548** |

(2) Advances paid and received that are not repaid in cash, and deferred income and prepaid expenses that do not meet the definition of financial liabilities, are not included.

**Note 15: Sales and operating revenue**

Sales and operating revenue consists of the following:

**SALES AND OPERATING REVENUE**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Sales | 7 431 | 6 760 |
| Research Tax Credit and other tax credit | 1 077 | 1 141 |
| **Total of revenues** | **8 509** | **7 901** |

The Group's sales comprise sales of Cellvizio® products and accessories (probes, software, and other), together with services.

**SALES BY TYPE OF PRODUCT**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Total sales of "equipements" | 2 301 | 2 683 |
| Total sales of "consumables" (probes) | 4 119 | 2 812 |
| Total sales of "services" | 1 011 | 1 265 |
| **Total of sales by type** | **7 431** | **6 760** |

Sales by geographic region as of December 31, 2019 are broken down as follows:

**SALES BY GEOGRAPHICAL AREA**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| EMEA (Europe, Middle-east, Africa) | 1 151 | 1 544 |
| *including France* | *268* | *335* |
| America | 3 717 | 3 618 |
| *including USA* | *3 434* | *3 263* |
| *including Latin America* | *283* | *355* |
| Asie | 2 562 | 1 599 |
| *including China* | *2 359* | *1 290* |
| *including Japan* | *41* | *62* |
| **Total sales by geographical area** | **7 431** | **6 760** |

For the purposes of geographical analysis, the management of the Group allocates sales revenue according to the place of delivery, or, in the case of services, according to the location of the customer's registered office.

At December 31, 2019, one distributor from the APAC region accounted for more than 31.7% of sales.

**Note 16: Payroll expenses**

The Group employed 101 persons as of December 31, 2019 compared with 100 persons as of December 31, 2018.

The employee benefits expense breaks down as follows:

**EMPLOYEE BENEFITS EXPENSE**

(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Wages and salaries, social security costs | 11 922 | 10 345 |
| Net pension costs variation | 27 | (10) |
| Share-based payment transaction expenses | 952 | 138 |
| **Total of employee benefits expense** | **12 902** | **10 474** |

**Note 17: Share-based payments**

Share-based payments concern all warrants (BSA/BSPCE), stock options (SO) and preferred shares (PS) awarded to employees, service providers and members of the Board of Directors.

They have been recorded as expenses since the award knowing that the terms for exercising BSPCEs and SOs are as follows for the plans awarded before 2017:

- 25% of the founders' warrants/stock options may be exercised starting on the first anniversary of their award;
- 25% of the founders' warrants/stock options may be exercised starting on the second anniversary of their award;
- 25% of the founders' warrants/stock options may be exercised starting on the third anniversary of their award;
- the remaining balance, i.e., 25% of the founders' warrants/stock options, may be exercised starting on the fourth anniversary of their award;
- no later than ten years from their issue, or seven years for stock options granted before 2011, it being specified that founders' warrants/stock options not yet exercised by the end of this ten-year period automatically become null and void.

The terms and conditions for exercising stock options are the following for plans awarded starting in 2017:

- 20% of the options at the end of the first year from the first anniversary date of their award; and
- 40% of the options at the end of the second year from the second anniversary date of their award; and
- 20% of the options at the end of the third and fourth years from the date of their award; and
- no later than ten (10) years from their award, it being specified that the options that have not yet been exercised at the end of this 10-year period automatically become null and void.

The terms and conditions for exercising warrants are as follows:

- 33.3% of the warrants may be exercised starting on the first anniversary of their award;
- 33.3% of the warrants may be exercised starting on the second anniversary of their award;
- the remaining balance, i.e., 33.3% of the warrants, may be exercised starting on the third anniversary of their award;
- Warrants not yet exercised within ten years of their issue automatically become null and void.

Regarding preference shares, the terms and conditions for exercise are described in the minutes of the Extraordinary General Meetings of May 4, 2016 in resolution 19 and October 5, 2018 in resolutions 14 and 15.
(https://www.maunakeatech.com/uploads/media/media_pdf/0001/03/PV%20AGM%205%20octobre%202018%20Rev.pdf)

The main characteristics are as follows:

The 2018 Preference Shares vested to their beneficiaries at the Acquisition Date will be convertible into new or existing ordinary shares at the Company's choice (the "Ordinary Shares"), at the request of each beneficiary concerned, at any time after the second anniversary of the Acquisition Date and no later than the fifth anniversary of the Acquisition Date (the "Conversion Period"), unless otherwise specified in the 2018 Preference Shares award plan or otherwise decided by the Board of Directors and notified to each holder of 2018 Preference Shares according to the following terms and conditions:

a .In the event of the Beneficiary's Departure between the Acquisition Date (inclusive) and the first anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into twenty Ordinary Shares;

b.in the event of the Beneficiary's Departure between the first anniversary of the Acquisition Date (inclusive) and the second anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into thirty-three Ordinary Shares;

c. in the event of the Beneficiary's Departure between the second anniversary (inclusive) and the third anniversary(exclusive) of the Acquisition Date, the conversion ratio will be determined as follows:

(i) if the Benchmark Price 1 is strictly less than the Floor Price, each Preference Share shall be convertible into thirty-three Ordinary Shares;

(ii) if the Benchmark Price 1 is strictly higher than the Intermediate Price, each Preference Share shall be convertible into sixty-six Ordinary Shares;

(iii) if the Benchmark Price 1 is between the Floor Price (inclusive) and the Intermediate Price (inclusive), each Preferred Share shall carry entitlement to the following number of Ordinary Shares:

$$33 + 33 \times \frac{\text{Reference Price 1} - \text{Floor Price}}{\text{Intermediate Price} - \text{Floor Price}}$$

where:
- the term 'Bottom Price' means 1.75 times the Allocation Price;
- the term 'Allocation Price' means the average of closure prices recorded on Euronext or any other main listing location for the Mauna Kea Technologies share over the 60 trading sessions prior to the allocation date of the relevant 2018 Preference Shares ('Allocation Date');
- the term 'Intermediate Price' means 2.5 times the Allocation Price; and
- the term 'Reference Price 1' means the highest average of closure prices for the share on Euronext or any other main listing location for the Mauna Kea Technologies share over a period of 60 consecutive trading sessions, calculated at any time from the Acquisition Date and until the second anniversary of the Acquisition Date;

d. in the event of the Beneficiary's Departure after the Holding Period, each Preference Share shall carry entitlement to the following number of Ordinary Shares:

(x) of the number of Ordinary Shares calculated in accordance with the provisions of paragraph 3.c) above as if the Departure of the beneficiary had occurred between the second and the third anniversary of the Acquisition Date, and;

(y) of the following number of Ordinary Shares:

(i )if the Reference Price 2 is strictly lower than the Floor Price: none;

(ii) if the Reference Price 2 is strictly greater than the Ceiling Price: the difference between one hundred Ordinary Shares and the number of Ordinary Shares determined in (x) (such that the sum of (x) and (y) equals 100);

(iii)if the Reference Price 2 is between the Floor Price (included) and the Ceiling Price (included): the difference, if positive, between:

$$-33 + 67 \times \frac{\text{Reference Price 2} - \text{Floor Price}}{\text{Ceiling Price - Floor Price}}; \text{ and}$$

- the number of Ordinary Shares determined under (x).

where:
- - the term 'Floor Price' means 2.45 times the Allocation Price;
- - the term 'Ceiling Price' means 3.5 times the Allocation Price; and
- - the term 'Reference Price 2' means the highest average of closure prices for the share on Euronext or any other main listing location for the Mauna Kea Technologies share over a period of 60 consecutive trading sessions, calculated at any time from the date of the first anniversary of the Acquisition Date and until the third anniversary of the Acquisition Date.

It should be noted that this conversion rate may be adjusted to take account of shares to be issued to protect the rights of holders of securities giving access to the Company's share capital, and the beneficiaries of Preference Shares, in accordance with applicable legal and regulatory provisions.

The Preference Shares may be converted only during the period of five years and six months following the expiration of the Holding Period (the “Holding Period”).

The detail of the share-based payments is presented in the table below:

| Type | Date of granting | Exercise price | Outstanding at 12/31/2017 | Number of shares | Exercised | Cancelled | Outstanding at 12/31/2018 | Potential number of shares |
|---|---|---|---|---|---|---|---|---|
| Options granted before January 1st, 2018 | | | 3 491 426 | | 854 000 | 1 487 442 | 1 149 984 | 2 275 813 |
| SO | 28/02/2018 | 3,12 € | | 300 000 | | 70 000 | 230 000 | 230 000 |
| SO | 24/07/2018 | 2,54 € | | 80 000 | | | 80 000 | 80 000 |
| SO | 19/09/2018 | 2,86 € | | 40 000 | | | 40 000 | 40 000 |
| SO | 12/11/2018 | 2,59 € | | 600 000 | | | 600 000 | 600 000 |
| SO | 28/11/2018 | 2,52 € | | 35 000 | | | 35 000 | 35 000 |
| BSA | 28/02/2018 | 3,12 € | | 55 000 | | | 55 000 | 55 000 |
| BSA | 22/03/2018 | 2,92 € | | 50 000 | | 50 000 | 0 | 0 |
| BSA | 12/11/2018 | 2,76 € | | 40 000 | | | 40 000 | 40 000 |
| AP | 10/10/2018 | | | 5 700 | | | 5 700 | 570 000 |
| AP | 12/11/2018 | | | 1 375 | | | 1 375 | 137 500 |
| | | | | 1 207 075 | 854 000 | 1 607 442 | 2 237 059 | 4 063 313 |

| Type | Date of granting | Exercise price | Outstanding at 12/31/2018 | Number of shares | Exercised | Cancelled | Outstanding at 12/31/2019 | Potential number of shares |
|---|---|---|---|---|---|---|---|---|
| Options granted before January 1st, 2019 | | | 2 237 059 | | - | 186 250 | 2 050 809 | 3 169 563 |
| SO | 07/02/2019 | 2,13 € | | 40 000 | | | 40 000 | 40 000 |
| SO | 19/05/2019 | 1,63 € | | 75 000 | | | 75 000 | 75 000 |
| BSA | 19/05/2019 | 1,84 € | | 170 000 | | | 170 000 | 170 000 |
| BSA BEI | 03/07/2019 | 1,89 € | | 1 450 000 | | | 1 450 000 | 1 450 000 |
| SO | 31/07/2019 | 1,68 € | | 127 500 | | | 127 500 | 127 500 |
| SO | 21/11/2019 | 0,86 € | | 55 000 | | | 55 000 | 55 000 |
| AP | 19/09/2019 | | | 150 | | 150 | - | 0 |
| AP | 20/11/2019 | | | 400 | | | 400 | 40 000 |
| | | | | 1 918 050 | 0 | 186 400 | 3 968 709 | 5 127 063 |

The other main assumptions used to determine share-based payment expenses using the Black-Scholes valuation model were as follows:

- Risk-free interest rate: Government borrowing rate (GFRN index),
- dividend: none;
- turnover: 15%;
- Volatility: 60% for warrants, founders' warrants and stock options granted before December 31, 2011, 35% for founders' warrants and stock options granted in 2012, 34% for founders' warrants and stock options granted in 2013, 32% and 33% for plans granted in 2014, 33% for plans granted in 2015, 29.99% for plans granted in 2016, 55% for plans granted in 2017, 59% for plans granted in 2018 and 50% for plans granted in 2019.

As of 2012, the volatility applied corresponds to the average historic volatility of a panel of listed companies in the sector of industry in which the Company operates and/or has a market capitalization and traded share volume comparable with those of the Company. Listed companies whose shares were traded for less than €1 were excluded from the panel.

The exercise price, estimated life and fair value of underlying shares at the award date of the warrants were used to value each category of share-based compensation.

Share-based payment expenses during the period break down as follows:

**DETAILS OF THE RESTATEMENT OF SHARE-BASED PAYMENTS**

(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Share-based payments (expense of the period) | 952 | 138 |
| | **952** | **138** |

**Note 18: External expenses**

18.1 Research & Development Department

**RESEARCH & DEVELOPMENT**

(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Purchases consumed | 68 | 59 |
| Employee benefits expenses | 2 205 | 2 525 |
| External expenses | 558 | 1 417 |
| Taxes | 26 | 36 |
| Net change in amortization and depreciation | 341 | 612 |
| Other | (38) | 3 |
| **Total of Research & Development** | **3 160** | **4 653** |

18.2 Sales & Marketing Department

**SALES & MARKETING**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Purchases consumed | 10 | (24) |
| Employee benefits expenses | 6 076 | 5 416 |
| External expenses | 2 521 | 2 839 |
| Net change in amortization and depreciation | 423 | 814 |
| Other | (52) | 52 |
| **Total of Sales & Marketing** | **8 978** | **9 097** |

As of December 31, 2019, the line item "Others" includes impairments of bad debts for €958 thousand and an impairment reversal of €1,057 thousand.

18.3 Administrative expenses

**ADMINISTRATIVE EXPENSES**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Purchases consumed | 64 | 52 |
| Employee benefits expenses | 3 013 | 1 828 |
| External expenses | 2 446 | 1 819 |
| Taxes | 111 | 108 |
| Net change in amortization and depreciation | 589 | 136 |
| Other | (37) | 7 |
| **Total of administrative expenses** | **6 187** | **3 953** |

Administrative expenses were up by 57% on 2018, from €3,953 thousand in 2018 to €6,187 thousand in 2019. This increase results from the full-year impact of investments made in the second half of 2018 to strengthen the management team.

**Note 19: Financial income and expenses**

Financial income and expenses break down as follows:

**FINANCIAL REVENUE AND EXPENSES**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Foreign exchange gains | 23 | 112 |
| Gains on cash equivalents | (3) | 3 |
| Gains on fair value reassessment | 500 | 2 |
| **Total of financial revenue** | **520** | **116** |
| Foreign exchange losses | (75) | (281) |
| Interest expenses | (597) | (481) |
| Other financial expenses | (1 485) | (3) |
| Loss on cah equivalents | (3) | (3) |
| Disount expenses | (606) | (138) |
| **Total of financial expenses** | **(2 765)** | **(903)** |
| **Total of financial revenue and expenses** | **(2 245)** | **(786)** |

Interest expenses mainly correspond to the interest on the IPF loans (repaid in full over the year) and EIB loan, as well as interest on lease liabilities according to IFRS 16.

Other financial expenses are related to the full repayment of the IPF loan for €1,391 thousand and the pre-financing of the Research Tax Credit for €94 thousand.

The gains on fair value adjustment correspond in full to the valuation difference of the EIB warrants (BSA) between the grant date and the revaluation at the closing date.

Discounting expenses correspond mainly to interest relating to the Oseo conditional advance.

**Note 20: Income tax**

Under current tax laws, the Group has total tax losses of €87,744 thousand that may be carried forward indefinitely in France and total tax losses of €43,299 thousand that may be carried forward for 20 years in the United States, i.e. a total of €131,043 thousand at December 31, 2019. The deferred tax asset base net of temporary passive differences was not capitalized as a precautionary measure, in accordance with the principles set out in Note 1 "Accounting principles".

The tax rate applicable to the Company is the rate in effect in France (28%). By convention, the deferred income tax rate used is 31%.

**TAX PROOF**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Profit / (loss) | (15 272) | (12 785) |
| Income tax expense | | |
| **Profit before tax** | **(15 272)** | **(12 785)** |
| **Theoritical tax expense 32,02%** | **(4 890)** | **(4 402)** |
| Other non-deductible expenses and tax-exempt income | 10 | 24 |
| Effect of tax rate differences | (114) | (18) |
| Deferred tax assets not recognised | 4 993 | 4 396 |
| **Actual income tax expense** | | |

**Note 21: Commitments**

Contractual obligations excluding operating leases and finance leases

The Company subcontracts the manufacturing of some of the sub-assemblies necessary for the manufacturing of its products with suppliers. In order to secure its operations, it has made commitments to purchase a certain quantity of sub-assemblies from certain suppliers as described in the table below:

**OBLIGATIONS PURSUANT TO OTHER AGREEMENTS**
(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Portion with terms of less than 1 year | 1 776 | 1 133 |
| Portion with terms of between 1 and 5 years | 2 744 | 172 |
| **Total of supplier commitments** | **4 520** | **1 305** |

*Obligations related to the EIB loan*

Following the financing agreement with the European Investment Bank (EIB) signed on June 20, 2019 for €22.5 million, the Company received the first instalment of €11.5 million on July 3, 2019.

The following instalments of €6 million and €5 million, respectively, will be available subject to achieving certain milestones, particularly related to commercial progress and the improvement of shareholders' equity:

- The second instalment of €6 million is subject to additional equity capital financing of €7.5 million and the achievement, over a rolling 12-month period, of €14 million of cumulative revenues. This second instalment will include 300,000 warrants (BSA). Repayment of the principal and capitalized interest will be made in full after the fifth year from the date of drawdown.
- The third instalment of €5 million is subject to additional equity capital financing of €15 million and the achievement, over a rolling 12-month period, of €24 million of cumulative revenues. The fixed interest rate includes a portion at 3% annually and a portion at 3% capitalized. Repayment of the principal and capitalized interest will be made in full after the fifth year from the date of drawdown.

This debt includes financial covenants.

The limited guarantees, taken by the European Investment Bank, cover the Company's trade receivables and inventories. No guarantee was given over Intellectual Property rights.

These contractual guarantees are being questioned due to the expected receipt of second instalment, which is not subject to achieving a level of revenues and should lead to the issuance of 500,000 stock warrants (BSAs).

**Note 22: Transactions with related parties**

The compensation presented below, which was granted to members of the Company's general management and other related parties, was recognized under expenses during the periods presented:

**RELATED PARTY TRANSACTIONS**

(Amounts in thousands of euros)

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| Wages and salaries - General direction | 571 | 281 |
| Share-based payments - General direction | 54 | 97 |
| Pension plan - General direction | 3 | 2 |
| Attendance fees - Executive officers | 241 | 233 |
| Share-base payments - Executive officers | 88 | 29 |

**Note 23: Earnings per share**

*Basic earnings per share are calculated by dividing the net earnings to which Company shareholders are entitled by the weighted average number of ordinary and preferred shares outstanding during the financial year.*

**EARNINGS PER SHARE**

| | 12/31/2019 | 12/31/2018 |
|---|---|---|
| **Profit / (loss) (in K€)** | **(15 272)** | **(12 785)** |
| Weighted average number of shares outstanding (in thousands) | 30 571 | 25 201 |
| **Earnings per share (in €)** | **(0,50)** | **(0,51)** |
| | | |
| Weighted average number of potential shares (in thousands) | 29 524 | 27 222 |

Instruments that grant rights to the share capital on a deferred basis (BSAs, BSPCEs or stock options) are considered antidilutive because they cause an increase in earnings per share. Thus, diluted earnings per share are identical to basic earnings per share.

**Note 24: Management of financial risk**

The main financial instruments used by the Group are financial assets, cash, and investment securities. The purpose of managing these instruments is to finance the Company's business activity. It is the Group's policy not to subscribe to financial instruments for speculative purposes.

The primary risks to which the Group is exposed are interest rate risk, credit risk and exchange rate risk.

*Exchange rate risk*

The main currency for which the Group is exposed to significant exchange rate risk is the US dollar.

The purpose of the Mauna Kea Technologies Inc. subsidiary established in the State of Massachusetts is to distribute and market the Group's products in the United States. To this end, it is fully financed by the parent company, with which it has established three agreements:

- a cash management agreement for a current account in USD;
- a distribution agreement;
- a services agreement (Management fees).

The Group's major exchange rate risk is linked to changes in the EUR/USD exchange rate. In fact, the Group markets the product and services in the USA through its subsidiary Mauna Kea Technologies Inc. Its revenues and expenses – including the purchases of Cellvizio and probes to Mauna Kea Technologies SA – are expressed in US dollars the operational currency of the subsidiary. As a result, the Group is exposed to changes in the EUR/USD exchange rate through that subsidiary.

A change in exchange rates has an impact on Group earnings and shareholders' equity in the same manner, as follows:

- A +10% change in the EUR/USD exchange rate would result in a rise in earnings of €499 thousand at December 31, 2019;
- A -10% change in the EUR/USD exchange rate would result in a drop in earnings of €(610) thousand at December 31, 2019.

*Liquidity risk*

See Note 1.9: Cash and cash equivalents

*Interest Rate Risk*

At December 31, 2019, the Company did not hold any investment securities, whose interest rate changes have a direct impact on the rate of return for these investments and the cash flows generated.

The EIB loan is at a fixed rate and therefore not subject to interest rate risk.

The repayable BPI/OSEO advances at a 2.45% interest rate for an overall, non-discounted amount of €2,904 thousand are detailed in Note 11: Borrowings and financial debts. They are not subject to interest rate risk.

*Credit Risk*

In the Company's experience, the payment of certain public financing of research expenditures is subject to credit risk.

The Company manages its available cash in a prudent manner. Cash and cash equivalents include cash on hand only.

Credit risk related to cash, cash equivalents, and current financial instruments is insignificant in light of the quality of the co-contracting financial institutions.

With regard to its customers, the Company has no significant concentration of credit risk. The Group has established policies that insure that its customers have an appropriate credit risk history.

*Fair value*

The fair value of financial instruments traded on an active market is based on the market price at the balance sheet date. The market prices used for financial assets held by the Company are the purchase prices in effect on the market at the valuation date.

The nominal value, minus provisions for impairment, of other payables and receivables is assumed to approach the fair value of those items.

**Note 25: Subsequent events**

*New authorizations*

On March 3, 2020, Mauna Kea Technologies obtained 510(k) authorization (K193416) in the United States from the Food and Drug Administration (FDA) as well as CE marking for the new generation endomicroscopy platform Cellvizio®, developed with the company's new proprietary architecture. This is the 18th 510(k) authorization from the U.S. FDA for the pCLE/nCLE Cellvizio® platform.

The new Cellvizio platform incorporates innovative modular design solutions to facilitate and better incorporate endomicroscopy in operating theaters as well as in the platforms of other manufacturers.

The hardware and software for the new platform has been completely redesigned to make it future-proof in particularly to allow the integration of artificial intelligence functionalities (deep learning) to assist in the interpretation of endomicroscopic images. The new ergonomy and considerably reduced size of the new Cellvizio means it can be easily integrated in advanced navigation, robot-assisted and laparoscopic surgery systems. This new system is also capable of integrating other proprietary endomicroscopic architectures, enabling imaging on other wavelengths intended for fluorescence image-guided surgery and molecular imaging.

*New funding*

On April 17, 2020, the Company obtained confirmation from the EIB that it could draw down the second instalment of €6,000 thousand pursuant to the contract.

On April 20, 2020, through its subsidiary Mauna Kea Inc. the Company was awarded a of €0.6 million under the Paycheck Protection Program in the United States.

*Covid-19 pandemic*

Due to the Covid-19 pandemic and the absolute necessity to safeguard the health of employees, a set of preventative measures has been implemented within the company. As of the date of the meeting of the Board of Directors, the majority of employees are working remotely.

From a financial point of view, all the measures proposed by the French Government have been reviewed and steps have been taken in France and in the USA to obtain additional financing (see section related to Going Concern).

At the closing date of the financial statements, the financial impacts of the COVID-19 epidemic on the 2020 financial year cannot be reliably estimated. As a result, certain planned spending in 2020 has been frozen.

### Consolidated financial statement prepared in accordance with IFRS as December 31, 2018

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the consolidated financial statements and the statutory auditors' report on the consolidated financial statements for the year ended December 31, 2018 are included for reference in this Universal Registration Document.

### Consolidated financial statements prepared under IFRS for the year ended December 31, 2017

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the consolidated financial statements and the statutory auditors' report on the consolidated financial statements for the year ended December 31, 2017 as presented in the 2017 annual financial report are included for reference in this Universal Registration Document.

### Table of the past five consolidated financial years

Table of results for the past five consolidated financial years (in €k)

| Type of indication / period | 12/31/2019 | 12/31/2018 | 12/31/2017 | 12/31/2016 | 12/31/2015 |
|---|---|---|---|---|---|
| Duration of the financial year | 12 months | 12 months | 12 months | 12 months | 12 months |
| I - Financial position at year-end | | | | | |
| a) Share capital | 1,223 | 1,008 | 974 | 800 | 647 |
| b) Number of shares issued | 5,357,142 | | | | |
| c) Number of bonds convertible into shares | | | | | |
| II - Comprehensive income from operations | | | | | |
| a) Sales excluding taxes | 7,431 | 6,760 | 6,687 | 8,787 | 8,547 |
| b) Profit/(loss) before tax, depreciation, amortization and provisions | -14,094 | -11,411 | -9,171 | -8,815 | -11,870 |
| c) Income tax | 0 | 0 | 0 | 0 | 0 |
| d) Profit/(loss) after tax, but before depreciation, amortization and provisions | -14,094 | -11,411 | -9,171 | -8,815 | -11,870 |
| e) Profit/(loss) after tax, depreciation, amortization and provisions | -15,272 | -12,785 | -10,245 | -9,744 | -12,643 |
| f) Amount of profits distributed | | | | | |
| g) Employee shareholding | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| III - Earnings per share | | | | | |
| a) Profit/(loss) after tax, but before depreciation and amortization | | | | | |
| b) Profit/(loss) after tax, depreciation, amortization and provisions | | | | | |
| c) Dividends paid per share | | | | | |
| IV - Employees: | | | | | |
| a) Number of employees | 101 | 100 | 90 | 76 | 91 |
| b) Total payroll | 11,922 | 10,324 | 8,874 | 8,744 | 11,515 |
| c) Amounts paid under pension commitments and share-based payments | 979 | 128 | 238 | 319 | 420 |

## 20.2 Annual statements

### 20.2.1 Company financial statements for the year ended December 31, 2019

# BALANCE SHEET AS OF DECEMBER 31, 2019

**A. Balance sheet – Assets**

| Rubrics | Gross amount | Amort. Prov. | Net 12/31/2019 | Net 12/31/2018 |
|---|---|---|---|---|
| Uncalled issued capital | | | | |
| INTANGIBLE ASSETS | | | | |
| Start-up costs | | | | |
| Development costs | | | | |
| Concessions, patents and similar rights | 893,097 | 645,710 | 247,388 | 351,210 |
| Goodwill | | | | |
| Other intangible assets | 30,350 | 11,207 | 19,143 | 7,643 |
| Advances, prepayments on intangible assets | | | | |
| PROPERTY, PLANT AND EQUIPMENT | | | | |
| Land | | | | |
| Buildings | 51,090 | 51,062 | 28 | 709 |
| Technical facilities, machinery and equipment | 1,399,806 | 1,056,968 | 342,838 | 243,806 |
| Other tangible assets | 1,145,689 | 929,593 | 216,096 | 296,830 |
| Assets under construction | 117,998 | | 117,998 | 148,444 |
| Advances and prepayments | | | | |
| LONG-TERM INVESTMENTS | | | | |
| Companies accounted for by the equity method | 23,077 | 23,077 | | |
| Other participating interests | | | | |
| Loans related to participating interests | 52,701,016 | 48,510,909 | 4,190,107 | 4,108,584 |
| Other fixed securities | | | | |
| Loans | | | | |
| Other long-term investments | 270,741 | | 270,741 | 267,193 |
| Fixed assets | 56,632,865 | 51,228,526 | 5,404,339 | 5,424,420 |
| INVENTORIES & WORK IN PROGRESS | | | | |
| Raw materials and supplies | 1,212,141 | 78,666 | 1,133,478 | 987,128 |
| Work in progress – goods | | | | |
| Work in progress – services | | | | |
| Semi-finished and finished goods | 1,689,664 | 89,110 | 1,600,554 | 1,332,279 |
| Goods | | | | |
| Advances and prepayments on orders | 186,786 | | 186,786 | 114,695 |
| RECEIVABLES | | | | |
| Trade receivables | 2,762,039 | 531,177 | 2,230,862 | 2,001,982 |
| Other receivables | 1,007,182 | | 1,007,182 | 2,671,335 |
| Capital subscribed and called but not paid | | | | |
| MISCELLANEOUS | | | | |
| Investment securities | | | | |
| Cash and cash equivalents | 9,896,492 | | 9,896,492 | 8,165,994 |
| ACCRUALS | | | | |
| Prepaid expenses | 132,599 | | 132,599 | 319,924 |
| CURRENT ASSETS | 16,886,903 | 698,953 | 16,187,950 | 15,593,336 |
| Deferred issuance expenses | | | | |
| Bond redemption premium | | | | |
| Unrealized foreign exchange losses | 2,093 | | 2,093 | 6,341 |
| **TOTAL** | **73,521,861** | **51,927,479** | **21,594,382** | **21,024,097** |

**B. Balance sheet – Liabilities**

| Rubrics | financial year 2019 | financial year 2018 |
|---|---|---|
| Share capital (of which paid up: 1,222,870) | 1,222,870 | 1,008,054 |
| Issue, merger and contribution premiums | 98,256,551 | 91,753,281 |
| Revaluation reserve | | |
| Legal reserves | | |
| Statutory or contractual reserve | | |
| Regulated reserve | | |
| Other reserve | 53,860 | (19,560) |
| Retained earnings | (86,657,811) | (74,786,685) |
| PROFIT/(LOSS) FOR THE YEAR | (15,534,771) | (11,871,126) |
| Investment subsidies | | |
| Regulated provisions | | |
| SHAREHOLDERS' EQUITY | (2,659,302) | 6,083,964 |
| Proceeds from the issue of participating securities | | |
| Conditional advances | 3,430,831 | 2,903,563 |
| OTHER EQUITY | 3,430,831 | 2,903,563 |
| Provisions for risks | 67,093 | 91,341 |
| Provisions for expenses | | 14,782 |
| PROVISIONS | 67,903 | 106,123 |
| FINANCIAL DEBTS | | |
| Convertible bonds | | |
| Other bonds | | |
| Loans and borrowings from credit institutions | | |
| Other loans and borrowings | 11,794,019 | 4,245,292 |
| Advances and prepayments received on current orders | | |
| OPERATING LIABILITIES | | |
| Trade payables | 2,272,799 | 2,023,248 |
| Tax and employee-related liabilities | 1,639,698 | 1,412,273 |
| OTHER LIABILITIES | | |
| Amount due on fixed assets and related accounts | 36,691 | 62,804 |
| Other payable | | |
| ACCRUALS | | |
| Deferred revenues | 145,584 | 209,060 |
| LIABILITIES | 15,888,791 | 7,952,675 |
| Unrealized foreign currency gains | 4,866,969 | 3,977,772 |
| TOTAL | 21,594,382 | 21,024,097 |

# I. INCOME STATEMENT AS OF DECEMBER 31, 2019

| Rubrics | 2019 financial year | | | 2018 financial year |
|---|---|---|---|---|
| | France | Exports | Total | |
| Sales of goods | | 8,473 | 8,473 | 89,549 |
| Sale of manufactured goods | 136,288 | 5,492,363 | 5,628,651 | 7,104,100 |
| Sales of finished products | 137,227 | 858,019 | 995,247 | 1,144,798 |
| NET SALES | 273,515 | 6,358,855 | 6,632,371 | 8,338,448 |
| Production in stock | | | 274,551 | (162,807) |
| Fixed asset production | | | | |
| Operating subsidies | | | | 2,861 |
| Reversals of imp., prov. (and amortization), cost transfers | | | 1,082,525 | 88,754 |
| Other income | | | 109,750 | 107,481 |
| OPERATING REVENUE | | | 8,099,198 | 8,374,736 |
| Purchases of goods (including customs duties) | | | | 302 |
| Change in stocks (goods) | | | | |
| Purchases of raw materials and other supplies | | | 1,351,633 | 1,633,394 |
| Change in stocks (raw materials and supplies) | | | (171,565) | (312,683) |
| Other purchases and external expenses | | | 6,298,484 | 6,018,692 |
| Taxes and similar payments | | | 173,768 | 161,661 |
| Wages and salaries | | | 4,821,421 | 4,888,217 |
| Social security expenses | | | 2,210,751 | 2,143,104 |
| Operating allowances: | | | | |
| Amortization on fixed assets | | | 283,326 | 238,046 |
| Impairment on fixed assets | | | | |
| Impairment on current assets | | | 128,024 | 346,103 |
| Provisions | | | | 57,000 |
| Other expenses | | | 1,104,084 | 257,335 |
| OPERATING EXPENSES | | | 16,199,926 | 15,431,172 |
| OPERATING REVENUE | | | (8,100,728) | (7,056,436) |
| JOINT VENTURES | | | | |
| Profits transferred in and losses transferred out | | | | |
| Profits transferred out and losses transferred in | | | | |
| FINANCIAL REVENUE | | | 532,331 | 432,553 |
| Financial revenue from participating interests | | | | |
| Revenue from other investments and long-term receivables | | | | |
| Other interest and similar revenue | | | 503,656 | 384,729 |
| Write-backs of provisions, cost transfers | | | 6,341 | 1,728 |
| Foreign exchange gains | | | 22,335 | 46,095 |
| Net proceeds from disposals of investment securities | | | | |
| FINANCIAL EXPENSES | | | 8,968,075 | 6,391,047 |
| Depreciation, amortization and provisions - financial items | | | 6,287,481 | 5,637,758 |
| Interest and similar expenses | | | 2,661,064 | 677,979 |
| Foreign exchange losses | | | 19,530 | 75,310 |
| Net expenses on disposals of investment securities | | | | |
| FINANCIAL NET INCOME | | | (8,435,744) | (5,958,494) |
| PROFIT BEFORE TAX | | | (16,536,472) | (13,014,930) |
| NON-RECURRING REVENUE | | | 42,911 | 3,844 |
| Non-recurring revenue from non-capital transactions | | | 42,719 | |
| Non-recurring revenue from capital transactions | | | 193 | 3,844 |
| Write-backs of provisions, cost transfers | | | | |
| NON-RECURRING EXPENSES | | | 118,552 | 1,104 |
| Non-recurring expenses on non-capital transactions | | | 114,948 | 35 |
| Non-recurring expenses on capital transactions | | | 3,605 | 1,069 |
| Depreciation, amortization and provisions exceptional items | | | | |
| NON-RECURRING INCOME (EXPENSE) | | | (75,641) | 2,740 |
| Employee profit-sharing | | | | |
| Income tax | | | (1,077,342) | (1,141,064) |
| TOTAL INCOME | | | 8,674,440 | 8,811,133 |
| TOTAL EXPENSES | | | 24,209,211 | 20,682,259 |
| **PROFIT OR LOSS** | | | **(15,534,771)** | **(11,871,126)** |

## II. APPENDIX

# 1 THE COMPANY'S ACTIVITY AND HIGHLIGHT OF THE FINANCIAL YEAR

## 1.1. The Company's activity

Established in 2000, Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The Company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. Its flagship product, Cellvizio, is a confocal miniprobe endomicroscopy system which provides physicians and researchers high-resolution images of tissues at the cellular level. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with practically all endoscopes.

## 1.2. Highlights of the financial year

The financial statements cover the financial year from 1/1/2019 to 12/31/2019, i.e. for a period of 12 months.

The financial debt was restructured in 2019. The IPF Partners financing, issued in February 2017 and again in May 2019 totaling €9 million, was fully repaid on June 28, 2019 for €10.7 million including early repayment fees. Financing of €22.5 million was contracted on June 20, 2019 with the European Investment Bank (EIB). The first instalment of this financing for €11.5 million, repayable in full after 5 years, was received on July 3, 2019. This loan, together with 1,450,000 warrants repayable in shares or cash, is intended to finance 50% of future research expenses.

In addition, a €7.5 million capital increase reserved for Johnson & Johnson Innovation Inc. through the issue of 5,357,142 new ordinary shares with a nominal value of €0.04 each, for an issue price of €1.40, raises this company's stake in Mauna Kea Technologies to 17.5% at the end of 17.5%. This capital increase is intended to fund day-to-day operations, particularly in the areas of clinical trials, development activities and sales and marketing in the United States.

# 2 MAJOR EVENTS SINCE THE END OF THE REPORTING PERIOD

On April 17, 2020, the Company obtained confirmation from the EIB that it could draw down the second instalment of €6 thousand pursuant to the contract.

Due to the Covid-19 pandemic and the absolute necessity to safeguard the health of employees, a set of preventative measures has been implemented within the company. As of the date of the meeting of the Board of Directors, the majority of employees are working remotely.

From a financial point of view, all the measures proposed by the French Government have been reviewed and steps have been taken in France and in the USA to obtain additional financing (see section related to Going Concern). At the closing date of the financial statements, the financial impacts of the COVID-19 epidemic on the 2020 financial year cannot be reliably estimated. As a result, certain planned spending in 2020 has been frozen.

# 3 ACCOUNTING RULES AND METHODS

The Company's annual financial statements were prepared according to the standards, principles and methods of the general accounting plan attached to regulation 2016(07) of the French Accounting Standards Authority (Autorité des Normes Comptables) of November 4, 2016, approved by order of November 2016, in accordance with the provisions of French legislation, in line with the principle of prudence and in accordance with the general rules for preparing and presenting the annual financial statements:

i. continuity of accounting methods from one financial year to another;
ii. independence of financial years;
iii. going concern.

These financial statements were approved by the Board of Directors at its meeting on April 27, 2020.

The going concern assumption was adopted by the Board of Directors taking into account the following elements:

- cash available at December 31, 2019 stood at €10 million;
- the drawdown of the second instalment of €6 million provided for under the contract signed with the EIB in 2019 following the withdrawal by the EIB of the sales condition associated with that drawdown;
- the payment on April 20 of a U.S. paycheck protection loan of approximately €0.6 million to MKT Inc.;
- the granting of a repayable advance and a PERSEE grant of €0.5 million in 2020;

- The receipt of the balance of the research tax credit for 2019 and the pre-financing of the research tax credit for an amount of €0.8 million;
- the sales outlook taking into account the impact of the Covid-19 crisis.

In this context, the Company considers that it is in a position to meet its commitments until December 31, 2020.

The accounting elements are valued according to the historical cost method.

The most significant accounting principles and methods, used in the preparation of the company financial statements are as follows:

## 3.1. Fixed assets

### 3.1.1. Property, plant and equipment and intangible assets

Patent expenses as well as research and development expenses incurred internally are recognized as expenses during the period. Property, plant and equipment and intangible assets are recognized at the cost of acquisition and their depreciation and amortization is calculated on the basis of their estimated useful lives.

The depreciation method and period by category of fixed assets is as follows:

| Category | Term | Method |
|---|---|---|
| Software packages | 1 to 3 years | Straight line method |
| Patents, Licenses, Trademarks | 10 years | Straight line method |
| Other property, plant and equipment: | | |
| - fixtures | 7 years | Straight line method |
| - tools | 2 to 7 years | Straight line method |
| - computer equipment | 3 years. | Straight line method |
| - furniture | 5 years | Straight line method |

### 3.1.2. Long-term investments and investment securities

The elements constituting the fixed assets were valued according to the historical cost method, which is marked by the use of nominal costs expressed in current euros. The gross value comprises the purchase price, excluding transaction costs. Where the inventory value is less than the gross value, a provision for impairment is recorded for the difference.

## 3.2. Evaluation of inventories

Inventories are valued at their cost of acquisition according to the following methods:

| Description | Methods |
|---|---|
| Raw materials | First-in first-out |
| Work in progress | Cost of work in progress |
| Finished products | Cost price, except for marketing costs |

The acquisition cost is comprised of:

- the purchase price, including customs duties and other non-recoverable taxes;
- post-deduction of trade rebates, deductions, cash discounts and other similar elements;
- transport, handling and storage costs (if justified by specific operating conditions);
- and other costs directly attributable to the acquisition.

The cost of production includes consumption of raw materials, direct costs, depreciation of assets used in production.

The demonstration equipment intended for sale in the short term is recognized in inventories.

Where applicable, stocks were impaired through provisions to take into account their realizable value on the reporting date.

### 3.3. Receivables

Receivables are recorded at their nominal value. A provision for impairment is made when the inventory value is less than the book value.

### 3.4. Provisions

Pursuant to the principle of prudence, provisions for risks and expenses are made to face probable outflows of resources in favor of third parties with no counterparty for the Company. These provisions are estimated by taking into consideration the most probable assumptions on the reporting date.

The Company has not chosen to recognize the provision for pension plan commitments.

### 3.5. Foreign currency transactions

The expenses and revenue in foreign currency are recorded for their corresponding value on the transaction date.

Foreign currency receivables and payables existing at year-end are converted at the exchange rate on this date. The conversion difference is recorded in the balance sheet under “Translation differences”.

Unrealized foreign exchange gains that have not been offset are recorded under provision for risks.

Foreign currency cash accounts existing at year-end are converted at the exchange rate on this date. The unrealized foreign exchange gains or losses resulting from this conversion are recorded in profit/loss.

### 3.6. Subsidies

The Company receives a certain number of forms of assistance, in the form of subsidies or conditional advances. Details of these aids are provided in the balance sheet notes 5.3.

Subsidies are recognized where there is reasonable assurance that the Company will comply with the conditions attached to the subsidies and that they will be received.

Subsidies are thus recognized when the documentation justifying the R&D expenses incurred has been accepted by the funding agency.

### 3.7. Research Tax Credit

Research tax credits are granted to companies by the French government in order to encourage them to conduct technical and scientific research. Companies that justify expenses that meet the required criteria (research expenses located in France or, since January 1, 2005, within the European Community or in another State party to the agreement on the European Economic Area that has a tax treaty with France containing an administrative assistance clause) benefit from a tax credit. Under the terms of Article 199 ter B (II) of the French General Tax Code, research tax credit receivables may be reimbursed immediately when incurred by small and medium-sized enterprises (SMEs) within the meaning of European Union (EU) law.

The Company has been receiving the Research Tax Credit since its establishment.

At the end of 2019, the Company recorded an Innovation Tax Credit applicable to expenses related to the prototype design and pilot installations of new products.

A framework agreement for the sale of receivables was signed in 2019 between Mauna Kea Technologies SA and the Fonds Commun de Titrisation Predirec Innovation 2020 (securitization mutual fund) enabling the sale of the 2017 and 2018 receivables as well as the latent receivable for the 2019 financial year. The amounts were sold at a 9% discount, partially recoverable up to 5% when paid by the State.

The sale of these receivables was recorded when ownership was transferred leading to the removal of these receivables from the balance sheet in exchange for the cash received.

A price supplement could be demanded by the securitization mutual fund, in particular if the State pays later than the agreed maturity date.

### 3.8. Deviation from general principles

#### 3.8.1. Change in the valuation methods

There was no notable change in the valuation method during the financial year.

#### 3.8.2. Change in the presentation methods

There was no notable change in the presentation method during the financial year.

### 3.9. Revenue Recognition

The revenue consists of 3 types of products:
- System sales;
- Consumable sales (probes);
- Maintenance and repair services.

The Company recognizes the sales of systems and consumables in revenue when ownership is transferred. This transfer of ownership is documented by a contract, a purchase order and a delivery note.

Whereas sales of maintenance services covering a period exceeding the financial year are recognized as deferred income. These deferred revenues are therefore spread over time according to the duration of the services contracted with the customer.

# 4 INFORMATION ON BALANCE SHEET ASSETS

## 4.1. Property, plant and equipment and intangible assets

### 4.1.1. Table of acquisitions and disposals during the financial year

| Figures expressed in euros | At 12/31/2018 | Acquisitions | Transfers between items and corrections +/- | Disposals | At 12/31/2019 |
|---|---|---|---|---|---|
| Start-up and development costs | | | | | |
| Other intangible fixed asset items | 911,947 | 11,500 | | | 923,447 |
| Total intangible assets | 911,947 | 11,500 | | 0 | 923,447 |
| Land | | | | | |
| Building and freehold land | | | | | |
| Building on non-freehold land | | | | | |
| Building installations, fixtures..... | 51,090 | | | | 51,090 |
| General installations and fixtures (1) | 506,866 | 5,477 | | 30,885 | 481,458 |
| Technical facilities, machinery and equipment (1) | 1,248,523 | 119,495 | 60,387 | 28,599 | 1,399,807 |
| Vehicles | | | | | |
| Office and computer equipment, furniture | 655,550 | 14,169 | 1,198 | 6,685 | 664,231 |
| Recoverable packaging and other items | | | | | |
| Total tangible assets | 2,462,030 | 139,141 | 61,585 | 66,169 | 2,596,587 |
| Property, plant and equipment in progress (1) | 148,444 | 31,138 | (61,585) | | 117,998 |
| Total assets in progress | 148,444 | 31,138 | (61,585) | | 117,998 |
| Prepayments | | | | | |
| **TOTAL** | **3,522,420** | **181,779** | **0** | **66,169** | **3,638,031** |

(1) These changes in the property, plant and equipment and intangible asset items from one financial year to another are due to asset acquisitions and asset sales completed by the Company for business purposes.

### 4.1.2. Depreciation and amortization table

The depreciation and amortization of property, plant and equipment and intangible assets are calculated on a straight line or digressive basis, according to the nature of the goods and based on the estimated useful life.

Technical depreciation and amortization table:

| Figures expressed in euros | At 12/31/2018 | Allowance | Decreases or write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Start-up and development costs | | | | |
| Other intangible assets | 553,094 | 103,823 | | 656,917 |
| Total amortization of intangible assets | 553,094 | 103,823 | | 656,917 |
| Land | | | | |
| Buildings | 50,381 | 681 | | 51,062 |
| General installations and fixtures | 330,924 | 45,793 | 30,385 | 345,832 |
| Technical facilities, machinery and equipment | 1,004,717 | 77,438 | 25,187 | 1,056,968 |
| Vehicles | | | | |
| Office and computer equipment, furniture<br>Recoverable packaging and other items | 534,661 | 55,591 | 6,492 | 583,761 |
| Total amortization of tangible assets | 1,920,683 | 179,503 | 62,564 | 2,037,623 |
| **TOTAL** | **2,473,777** | **283,326** | **62,564** | **2,694,540** |

### 4.1.3. Provisions for fixed asset impairment

See Section 5.2. Statement of provisions.

## 4.2. Long-term investments

Table of transactions for the financial year:

| Figures expressed in euros | Gross Value as of 12/31/2018 | Acquisitions and transfers between items | Sales and transfers between items | Gross Value At 12/31/2019 | Provisions | Net Value as of 12/31/2019 |
|---|---|---|---|---|---|---|
| MKT Inc. shares and MKT Inc. cash management account * | 46,357,181 | 6,366,911 | | 52,724,093 | 48,533,986 | 4,190,107 |
| Loans and other long-term investments | 267,193 | 3,548 | | 270,741 | | 270,741 |
| **TOTAL** | **46,624,374** | **6,370,459** | | **52,994,834** | **48,533,986** | **4,460,848** |

(*) MKT Inc. shares represented €23,077 at end-2018 and end-2019, fully impaired in 2018 and 2019. The MKT Inc. cash management account is written down to the net position of the subsidiary.

### 4.3. Inventories of goods and work in progress

At the end of each financial year, inventories and work in progress of finished goods include certain assets related to goods that no longer appear in our catalogue. These assets are held by the Company for use by After-Sales Customer Service. They are impaired by 80%.

The inventory amount is broken down as follows:

| Figures expressed in euros | Gross Amount | Depreciation | Balance at |
|---|---|---|---|
| Raw materials | 1,212,141 | 78,665 | 1,133,475 |
| Finished products | 1,689,664 | 89,110 | 1,600,554 |
| **TOTAL** | **2,901,805** | **167,776** | **2,734,029** |

### 4.4. Provisions for impairment of inventories and receivables

See Section 5.2. Statement of provisions.

### 4.5. Maturity of receivables

The gross value of receivables held by the Company amounts to €56,873,577 as of 12/31/2019 and can be broken down as follows:

| Figures expressed in euros | Gross Amount | At no more than one year | At more than one year |
|---|---|---|---|
| FIXED ASSETS: | 52,971,757 | | 52,971,757 |
| Loans related to participating interests | 52,701,016 | | 52,701,016 |
| Loans | | | |
| Other long-term investments | 270,741 | | 270,741 |
| CURRENT ASSETS: | 3,901,820 | 3,370,643 | 531,177 |
| Receivables | 2,230,862 | 2,230,862 | |
| Doubtful receivables | 531,177 | | 531,177 |
| Personnel and related accounts | 21,311 | 21,311 | |
| Social security bodies | 8,004 | 8,004 | |
| Statement: various taxes | 777,974 | 777,974 | |
| Group companies and associates | | | |
| Sundry debtors | 199,892 | 199,892 | |
| Prepaid expenses | 132,599 | 132,599 | |
| **TOTAL** | **56,873,577** | **3,370,643** | **53,502,934** |
| Amounts of loans granted during the year | | | |
| Amounts of repayments received during the year | | | |
| Loans and advances granted to partners (natural persons) | | | |

### 4.6. Trade receivables

| RECEIVABLES | Gross amount | Amort. Prov. | Net 12/31/2019 | Net 12/31/2018 |
|---|---|---|---|---|
| Trade receivables | 2,762,039 | 531,177 | 2,230,862 | 2,001,982 |
| Other receivables | 1,007,182 | | 1,007,182 | 2,671,335 |
| Capital subscribed and called but not paid | | | | |
| TOTAL | 3,769,221 | 531,177 | 3,238,044 | 4,673,317 |

Including Group receivables:

| Figures expressed in euros | 2019 | 2018 |
|---|---|---|
| Mauna Kea Technologies Inc | 802,184 | 1,302,005 |
| **TOTAL** | **802,184** | **1,302,005** |

Provisions are determined per the terms and conditions outlined in Section 5.2.5.

### 4.7. Accrued revenue

The amount of accrued revenue included in the following balance sheet items is:

| Figures expressed in euros | At 12/31/2019 | At 12/31/2018 |
|---|---|---|
| Receivables – Invoices to be raised | 5,945 | 940,223 |
| Accrued revenue | | 118,000 |
| **TOTAL** | **5,945** | **1,058,223** |

### 4.8. Investment securities

As of December 31, 2019, the Company held no money market funds.

### 4.9. Accruals

Prepaid expenses

Prepaid expenses amount to €132,599.

| Figures expressed in euros | At 12/31/2019 | At 12/31/2018 |
|---|---|---|
| Operating expenses | 132,599 | 319,924 |
| Financial expenses | | |
| Non-recurring expenses | | |
| **TOTAL** | **132,599** | **319,924** |

Translation differences

| DIFFERENCE ON THE ASSET SIDE | | DIFFERENCE ON THE LIABILITY SIDE | |
|---|---|---|---|
| | Euros | | Euros |
| Decrease in receivables | 1,592 | Decrease in liabilities | 1,996 |
| Increase in liabilities | 501 | Increase in receivables | 4,864,973 |
| **TOTAL** | **2,093** | **TOTAL** | **4,866,969** |

## 5 INFORMATION ON BALANCE SHEET LIABILITIES

### 5.1. Equity

**Share capital**
The share capital is set at one million two hundred twenty-two thousand eight hundred sixty-nine euros and sixty cents (€1,222,869.60). It is comprised of 30,571,740 shares with a nominal value of €0.04 each.

This figure does not include stock warrants (BSAs), founders' warrants (BSPCEs) or stock options (SOs) granted to certain investors and natural persons, who may or may not be employees of the Company.

The table below shows the history of the Company's share capital since December 31, 2018

| Type of transaction | Issued capital (€K) | Share premium (€K) | Number of shared comprising the issued capital |
|---|---|---|---|
| As of December 31, 2018 | 1,008 | 91,753 | 25,201 |
| Reserved capital increase | 214 | 6,530 | 5,357 |
| Preference shares | 1 | -1 | 13 |
| BSA | 0 | 47 | 0 |
| Reserve transferred | | -73 | |
| **Total as of December 31, 2019** | **1,223** | **98,256** | **30,571** |

On December 19, 2019, Johnson & Johnson (JJDC Inc.) subscribed to a capital increase for cash, totaling €7,500 thousand, i.e. 5,357,142 new shares at an issue price of €1.40. The share premium of €7,286 thousand was charged against the related issuance expenses, i.e. €756 thousand.

**Stock warrants, stock options and preferred stock**

Since its formation, the Company issued “Stock Warrants” (BSA), stock warrants for its employees (“BSPCE” and others) as well as stock options (SO) and free performance shares (PS), the changes since December 31, 2017 are represented below.

In 2018, the Company issued a new free preference share plan, the terms of which have been approved by the shareholders at the General Meeting of October 5, 2018, and new stock options and stock warrants plans.

The Company also opened, in December 2017, an equity financing facility with Kepler Cheuvreux covering a maximum number of 2,250,000 shares available for subscription over a maximum period of 24 months. The PACEO financing contract with Kepler Chevreux matured on December 4, and has not been renewed.

| Type | Date of granting | Exercise price | Outstanding at 12/31/2018 | Number of shares | Exercised | Cancelled | Outstanding at 12/31/2019 | Potential number of shares |
|---|---|---|---|---|---|---|---|---|
| Options granted before January 1st, 2019 | | | 2 237 059 | | - | 186 250 | 2 050 809 | 3 169 563 |
| SO | 07/02/2019 | 2,13 € | | 40 000 | | | 40 000 | 40 000 |
| SO | 19/05/2019 | 1,63 € | | 75 000 | | | 75 000 | 75 000 |
| BSA | 19/05/2019 | 1,84 € | | 170 000 | | | 170 000 | 170 000 |
| BSA BEI | 03/07/2019 | 1,89 € | | 1 450 000 | | | 1 450 000 | 1 450 000 |
| SO | 31/07/2019 | 1,68 € | | 127 500 | | | 127 500 | 127 500 |
| SO | 21/11/2019 | 0,86 € | | 15 000 | | | 15 000 | 15 000 |
| AP | 19/09/2019 | | | 150 | | 150 | - | 0 |
| AP | 20/11/2019 | | | 400 | | | 400 | 40 000 |
| | | | | 1 878 050 | 0 | 186 400 | 3 928 709 | 5 087 063 |

* Of which 850,000 warrants exercised as part of PACEO financing set up in December 2017

Following the consolidation of shares (four old shares for a new one) on May 25, 2011, four stock warrants, founders' warrants or stock options granted before that date are needed to subscribe for one new share. For warrants and options granted after that date, the ratio is one to one.

Starting from July 2014, the Company could no longer issue any new BSPCE plans, because it had exceeded the threshold of €150 million in market capitalization more than three years ago.

The terms and conditions for exercising preference shares are described in the minutes of the Extraordinary General Meetings of May 4, 2016 in resolution 19 and October 5, 2018 in resolutions 14 and 15 (https://www.maunakeatech.com/uploads/media/media_pdf/0001/03/PV%20AGM%205%20octobre%202018%20Rev.pdf).

**Company's buyback of its own shares**

The Extraordinary General Meeting of July 5, 2019, authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with the provisions of Article L. 225-209 et seq. of the French Commercial Code and in accordance with the General Regulation of the Autorité des Marchés Financiers (AMF) under the terms and conditions described below:

**Objectives of the share buyback program**:

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be concluded with an investment services provider, in accordance with a Code of Conduct approved by the AMF;
- to meet the obligations related to stock option, free share award, or employee savings plans, or other awards of shares to the employees and executives of the Company or the companies associated with it;
- to tender shares upon exercise of the rights attached to securities giving access to the share capital;
- to purchase shares to hold for their subsequent exchange or use as consideration in potential acquisitions; or
- conduct transactions for any purpose that may be authorized by law or any market practice that may be permitted by the market authorities;

**Maximum purchase price**: €30 per share excluding fees and commissions, with a total limit of €5,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

**Summary of the shares purchased and sold over the year:**

| | 2019 | | | | |
|---|---|---|---|---|---|
| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter | Total |
| Securities purchased | 188 271 | 160 904 | 387 291 | 359 400 | 1 095 866 |
| Price | 2,02 | 1,67 | 1,57 | 1,02 | |
| Total amount (in K€) | 381 | 268 | 608 | 367 | 1 624 |
| Securities sold | 173 316 | 169 636 | 366 040 | 389 907 | 1 098 899 |
| Price | 2,05 | 1,69 | 1,58 | 1,02 | |
| Total amount (in K€) | 356 | 286 | 579 | 399 | 1 620 |

At December 31, 2019, the Company held 35,786 Mauna Kea Technologies shares acquired at an average price of €1.37 equal to the realizable value on December 31, 2019.

Treasury shares are recognized in long-term investments.

**Appropriation of earnings for FY 2018:**

The financial statements for the 2018 financial year showed a net loss of €(11,871,126). Following the decision of the Annual General Meeting on July 5, 2019 approving the financial statements, this loss was allocated to retained earnings.

## 5.2. Statement of provisions

Details of the provisions by type are as follows:

### 5.2.1. Provisions for personnel disputes

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Provisions for personnel disputes | 85,000 | | 20,000 | 65,000 |
| **TOTAL** | **85,000** | | **20,000** | **65,000** |

The reversal of the provision has been fully utilized.

### 5.2.2. Provisions for risks

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Provisions for foreign exchange losses | 6,341 | 2,093 | 6,341 | 2,093 |
| **TOTAL** | **6,341** | **2,093** | **6,341** | **2,093** |

### 5.2.3. Provisions for expenses

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Provision for software update | 14,782 | | 14,782 | |
| **TOTAL** | **14,782** | **0** | **14,782** | **0** |

This provision intended to cover a former risk has not been utilized.

### 5.2.4. Provisions for fixed asset impairment

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Provision for long-term investments | 42,248,598 | 6,285,388 | | 48,533,986 |
| **TOTAL** | **42,248,598** | **6,285,388** | | **48,533,986** |

During the 2019 financial year, a net advance of €6,367 thousand was granted to the subsidiary Mauna Kea Technologies Inc. The total amount of advances stood at €52,701,016 at end-2019. This amount has been provisioned for the negative net asset value of the subsidiary, i.e. €48,534 thousand.

#### 5.2.5. Provisions for impairment of inventories

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Raw materials | 53,449 | 25,217 | | 78,665 |
| Finished products | 82,833 | 6,277 | | 89,110 |
| TOTAL | 136,282 | 31,493 | | 167,775 |

#### 5.2.6. Provisions for impairment of receivables

| Figures expressed in euros | At 12/31/2018 | Allowance | Write-backs | At 12/31/2019 |
|---|---|---|---|---|
| Doubtful receivables | 1,445,621 | 96,200 | (1,010,643) | 531,177 |
| Other receivables | | | | |
| **TOTAL** | **1,445,621** | **96,200** | **(1,010,643)** | **531,177** |

### 5.3. Financial debts

| Figures expressed in euros | 31 12 2018 | + | - | 31 12 2019 |
|---|---|---|---|---|
| Repayable advance BPI (ex Oseo) | 2 903 563 | | | 2 903 563 |
| Accrued interests on repayable advance | | 527 268 | | 527 268 |
| Total of other equity | 2 903 563 | 527 268 | - | 3 430 831 |
| Loan IPF | 4 000 000 | | 4 000 000 | - |
| Loan BEI | - | 11 500 000 | | 11 500 000 |
| Accrued interests on loan BEI | 233 981 | 282 708 | 233 981 | 282 708 |
| Deposits received | 11 311 | | | 11 311 |
| Total of loans and financial debts | 4 245 292 | 11 782 708 | 4 233 981 | 11 794 019 |

#### 5.3.1. BPI advances (formerly OSEO Fi)

On May 31, 2010, Mauna Kea Technologies obtained a repayable innovation loan in the amount of €3,416 thousand from OSEO as part of the PERSEE project. The PERSEE project aims to develop, validate and then market a device capable of improving diagnostic and preoperative assessment techniques for cancer patients. The first payments of the loan were as follows:

- first payment of €454 thousand on May 31, 2010,
- second payment of €1,138 thousand on December 21, 2011,
- third payment of €685 thousand on May 29, 2013,
- fourth payment of €626 thousand on December 22, 2016,

The fifth payment of €512 thousand has been delayed and should be received following the last key stage corresponding to the presentation of the clinical trial results. The advances granted carry interest at a rate of 2.45%.

The 2010 contract between Oseo, now BPI France, and the Company stipulates that the first repayment should take place once sales of €2,500 thousand on new products are reached. The end of this project has been delayed several times and is not expected at end-2020. The provisional repayment schedule for the advance could therefore be established and accrued interest recognized for the first time in 2019.

The amount to repay, based on the new expected repayment schedule, will be €4,961 thousand, including capitalized expenses. If no repayment occurs within 10 years of the first aid payment, Mauna Kea will be released from any obligation to pay a financial return. In addition, if the cumulative sales amount is greater than €50,000 thousand, 2% of the sales generated must be paid over fifteen years.

In addition, the specific contract between BPI France (formerly Oseo) and Mauna Kea stipulates in Article 4.3 that in the event of a failure by the Company to comply with any of its obligations as listed in the contract, of any irregular tax and social security situation, of inaccurate or false declarations, of a contribution, merger, demerger, transfer of control or of assets of the Company, Mauna Kea SA must repay in advance the discounted value.

### 5.3.2. Loans

The loan contracted with IPF Partners in February 2017 and again in May 2019 totaling €9 million, was fully repaid on June 28, 2019 for €10,700 thousand including early repayment fees.

Following the €22,500 thousand financing agreement signed with the European Investment Bank (EIB) on June 20, 2019, the Company received the first instalment of €11,494 thousand net on July 3, 2019.
The following instalments of €6,000 thousand and €5,000 thousand, respectively, will be available subject to achieving certain milestones.

The 1st instalment is accompanied by the issuance of stock warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of October 5, 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants may be exercised until the twentieth anniversary of their issuance, i.e. July 3, 2039.

### 5.4. Liabilities repayment schedule

| LIABILITIES | Gross amount end of financial year | Less than 1 year | 1 to 5 years | At more than 5 years |
|---|---|---|---|---|
| Convertible bonds | | | | |
| Other bonds | | | | |
| Loans and borrowings from credit institutions: | | | | |
| repayable within a maximum of one year at inception | | | | |
| repayable after more than one year at inception | | | | |
| Other loans and borrowings | 11,794,019 | 11,311 | 11,782,708 | |
| Trade payables | 2,272,799 | 2,272,799 | | |
| Personnel and related accounts | 805,287 | 805,287 | | |
| Social security and other welfare agencies | 708,209 | 708,209 | | |
| State and other public authorities: | | | | |
| Income tax | | | | |
| Value added tax | 2,816 | 2,816 | | |
| Guaranteed bonds | | | | |
| Other taxes and related accounts | 123,386 | 123,386 | | |
| Amount due on fixed assets and related accounts | | | | |
| Group companies and associates | 5,000 | | | 5,000 |
| Other payable | 31,690 | 31,690 | | |
| Liabilities representing borrowed securities or securities provided as collateral | | | | |
| Deferred revenues | 145,584 | 145,584 | | |
| **TOTAL** | **15,888,790** | **4,101,082** | **11,782,708** | **5,000** |
| Loans taken out during the financial year | 11,500,000 | | | |
| Loans repaid during the financial year | 4,000,000 | | | |

### 5.5. Trade payables

| Figures expressed in euros | At 12/31/2019 | At 12/31/2018 |
|---|---|---|
| Group suppliers | | |
| Suppliers in France | 679,926 | 805,814 |
| International suppliers | 692,614 | 90,215 |
| Suppliers whose invoices are not yet received | 900,258 | 1,127,218 |
| **Total trade payables** | **2,272,798** | **2,023,248** |

### 5.6. Accrued expenses

The amount of accrued expenses included in the following balance sheet items is:

| Rubrics | 2019 financial year | 2018 financial year |
|---|---|---|
| OPERATING LIABILITIES | | |
| Trade payables | 900,258 | 1,127,218 |
| Tax and employee-related liabilities | 1,259,461 | 1,108,303 |
| FINANCIAL DEBTS | | |
| Convertible bonds | | |
| Other bonds | | |
| Loans and borrowings from credit institutions | 809,976 | 233,981 |
| Other loans and borrowings (of which loans to individuals: ) | | |
| Advances and prepayments received on current orders | | |
| OTHER LIABILITIES | | |
| Amount due on fixed assets and related accounts | | |
| Other payable | | |
| ACCRUALS | | |
| Deferred revenues | | |
| **LIABILITIES** | **2,969,695** | **2,469,502** |

### 5.7. Accruals

#### 5.7.1. Deferred revenues

Deferred revenue breaks down as follows:

| Figures expressed in euros | At 12/31/2019 | At 12/31/2018 |
|---|---|---|
| Operating revenue | 145,584 | 209,060 |
| Financial revenue | | |
| Non-recurring revenue | | |
| **TOTAL** | **145,584** | **209,060** |

#### 5.7.2. Translation differences

See Section 4.9

### 5.8. Amount due to related companies

The Company has no liability towards its subsidiary.

## 6 INFORMATION ON THE INCOME STATEMENT

### 6.1. Breakdown of the net sales amount

Sales for FY 2019 break down as follows:

| Figures expressed in euros | 2019 financial year | | | 2018 Financial year |
|---|---|---|---|---|
| | France | EEC + Export | Total | Total |
| Sales of goods | | 8,473 | 8,473 | 89,549 |
| Sales of finished products | 136,288 | 5,492,363 | 5,628,651 | 7,104,100 |
| Sales of finished products | 137,227 | 858,019 | 995,247 | 1,144,798 |
| **Sales** | **273,515** | **6,358,855** | **6,632,370** | **8,338,448** |
| % | 4% | 96% | 100.00% | |

### 6.2. Other operating revenue

| Figures expressed in euros | At 12/31/2019 | At 12/31/2018 |
|---|---|---|
| Production in stock | (274,551) | (162,807) |
| Fixed asset production | | |
| Other management revenue and operating subsidies | | 2,861 |
| Write-backs of depreciation and amortization, provisions, cost transfers and other revenue | 1,082,525 | 88,754 |
| Other income | 109,750 | 107,481 |
| **TOTAL** | **917,724** | **36,289** |

Former receivables now classified as bad debts were subject to a provision reversal of €935 thousand.

### 6.3. Compensation of the statutory auditors

Depending on their mission statements, the summary of fees of the statutory auditors for the current and previous financial years is as follows:

| Amount in euros | 2019 financial year | | 2018 financial year | |
|---|---|---|---|---|
| | EY | EXCO | EY | EXCO |
| Audit | | | | |
| Statutory auditors, certification and review of the annual financial statements and the consolidated financial statements | | | | |
| Mauna Kea Technologies SA | 50,230 | 49,980 | 49,250 | |
| Fully consolidated subsidiaries | 34,760 | | 34,075 | 49,000 |
| **Sub-Total** | **84,990** | **49,980** | **83,325** | **49,000** |
| Others services rendered by the network to the fully consolidated subsidiaries | | | | |
| Services other than account certification (SACC) | 32,000 | 6,000 | 46,600 | |
| **Sub-Total** | **32,000** | **6,000** | **46,600** | |
| **Total** | **116,990** | **55,980** | **129,925** | **49,000** |

### 6.4. Net financial income

Net financial income for the year was €(8,435,744) thousand and breaks down as follows :

| Rubrics | 2019 financial year | 2018 Financial year |
|---|---|---|
| **FINANCIAL REVENUE** | **532,331** | **432,553** |
| Financial revenue from participating interests | | |
| Revenue from other investments and long-term receivables | | |
| Other interest and similar revenue | 503,656 | 384,729 |
| Write-backs of provisions, cost transfers | 6,341 | 1,728 |
| Foreign exchange gains | 22,335 | 46,095 |
| Net proceeds from disposals of investment securities | | |
| **FINANCIAL EXPENSES** | **8,968,075** | **6,391,047** |
| Depreciation, amortization and provisions - financial items | 6,287,481 | 5,637,758 |
| Interest and similar expenses | 2,661,064 | 677,979 |
| Foreign exchange losses | 19,530 | 75,310 |
| Net expenses on disposals of investment securities | | |
| **FINANCIAL NET INCOME** | **(8,435,744)** | **(5,958,494)** |

Financial allowances are mainly related to the impairment of current account advances to the subsidiary Mauna Kea Technologies Inc. for €6,285,388.

### 6.5. Non-recurring income

The non-recurring income of €(75,641) for the financial year breaks down as follows:

| Rubrics | 2019 financial year | 2018 financial year |
|---|---|---|
| **NON-RECURRING REVENUE** | **42,911** | **3,844** |
| Non-recurring revenue from non-capital transactions | 42,719 | |
| Non-recurring revenue from capital transactions | 193 | 3,844 |
| Write-backs of provisions, cost transfers | | |
| **NON-RECURRING EXPENSES** | **118,552** | **1,104** |
| Non-recurring expenses on non-capital transactions | 114,948 | 35 |
| Non-recurring expenses on capital transactions | 3,605 | 1,069 |
| Depreciation, amortization and provisions exceptional items | | |
| **RECURRING INCOME (EXPENSE)** | **(75,641)** | **2,740** |

### 6.6. Income tax

#### 6.6.1. Tax situation

As of December 31, 2019, the Company has a tax loss carry forward of €87,805,359.

#### 6.6.2. Deferred taxes

| BASES (in euros) | Opening balance | Changes in net income for the financial year | Closing balance |
|---|---|---|---|
| Differences between the tax regime and the accounting treatment of some revenues and expenses: | | | |
| Social security contribution | | | |
| Other provisions for risks | 6,341 | (4,248) | 2,093 |
| **TOTAL** | **6,341** | **(4,248)** | **2,093** |

#### 6.6.3. Tax credits

The Company benefits from the provisions of Articles 244 quarter B and 49 septies F of the French General Tax Code relating to research tax credits. The Research Tax Credit amount for the 2019 financial year was €997,342.The Innovation Tax credit stood at €80,000 with respect to the financial year.

# 7 MISCELLANEOUS INFORMATION

## 7.1. Average number of salaried and temporary employees

Over the 2019 financial year, the average number of employees broke down as follows:

| 2019 financial Year | Workforce |
|---|---|
| Executives | 61 |
| Supervisors, technicians and employees | 9 |
| Operators | 2 |
| **TOTAL** | **72** |

## 7.2. List of subsidiaries and investments

| Companies concerned | Issued capital | Capital held | Equity including profit/(loss) | Profit /(loss) |
|---|---|---|---|---|
| Mauna Kea Technologies Inc. (*) | 30,000 | 100% | -54,497,156 | -5,934,620 |

(*) The amounts are shown in US dollars

## 7.3. Information on related parties

There is no information on transactions between related parties as current transactions are excluded from the list of transactions with related parties.

## 7.4. Compensation of administrative bodies

The compensation of the management bodies is not provided as this would reveal individual compensation.

## 7.5. Financial commitments

### 7.5.1. Commitments given

- To BPI France

Mauna Kea has undertaken to pay BPI France (formerly Oseo) financial returns determined on the basis of revenue forecasts generated by operating the newly developed devices (PERSEE project).

To date the advances granted stand at €2,903 thousand and €513 thousand remains to be received at the end of this project. The end of the research program has been delayed to October 30, 2020 without change to the repayment terms and conditions.

As soon as the sales threshold of €2,500 thousand is crossed, Mauna Kea must reimburse €4,691 thousand including capitalized interest at a rate of 2.45% over a period of 5 years.

If no repayment occurs within 10 years of the first aid payment, Mauna Kea will be released from any obligation to pay a financial return.

In addition, if the cumulative sales amount is greater than €50,000 thousand, 2% of the sales generated must be paid over fifteen years.

In addition, the specific contract between BPI France (formerly Oseo) and Mauna Kea stipulates in Article 4.3 that in the event of a failure by the company to comply with any of its obligations as listed in the contract, of any irregular tax and social security situation, of inaccurate or false declarations, of a contribution, merger, demerger, transfer of control or of assets of the Company, Mauna Kea SA must repay in advance the discounted value.

- To the European Investment Bank (EIB)

Following the financing agreement with the European Investment Bank (EIB) signed on June 20, 2019 for €22.5 million, the Company received the first instalment of €11.5 million on July 3, 2019.

The 1st instalment is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of October 5, 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants (BSA) may be exercised until the twentieth anniversary of their issuance, i.e. July 3, 2039.

The following instalments of €6 million and €5 million, respectively, will be available subject to achieving certain milestones, particularly related to commercial progress and the improvement of shareholders' equity:

The second instalment of €6 million is subject to additional equity capital financing of €7.5 million and the achievement, over a rolling 12-month period, of €14 million of cumulative revenues. This second instalment will include 300,000 warrants (BSA). Repayment of the principal and capitalized interest will be made in full after the fifth year from the date of drawdown.

The third instalment of €5 million is subject to additional equity capital financing of €15 million and the achievement, over a rolling 12-month period, of €24 million of cumulative revenues. The fixed interest rate includes a portion at 3% annually and a portion at 3% capitalized. Repayment of the principal and capitalized interest will be made in full after the fifth year from the date of drawdown.

This debt includes financial covenants.

The limited guarantees, taken by the European Investment Bank, cover the Company's trade receivables and inventories. No guarantee was given over Intellectual Property rights.

As part of the discussions leading to the EIB agreement for the drawdown of the second instalment, the guarantees related to this instalment were modified.

- Sale of Research Tax Credit receivables

The Research Tax Credit receivables relating to financial year 2018 representing €1,097 thousand was sold on May 28, 2019; retention of a guarantee was recorded in this regard for €99 thousand. At end-January 2020, the financial institution had not received payment of this receivable whose maturity was on that date. The financing line therefore carries interest at 4.25% from February 2020.

The latent Research Tax Credit relating to financial year 2019 has been sold on October 24, 2019 for €487 thousand, with the retention of a guarantee of €48 thousand. The maturity date of this receivable is December 31, 2020.

If the receivable is not paid on its scheduled maturity, MKT SA is liable for interest at 4.25%.

- To partners

| Commitments given | Total | -1 year | from 1 to 5 years | +5 years |
|---|---|---|---|---|
| Related to leases | 1,281,990 | 441,211 | 840,779 | |
| Related to supply contracts | 4,520,058 | 1,775,632 | 2,744,426 | |
| | **5,802,048** | **2,216,843** | **3,585,205** | |

### 7.5.2. Commitments received

No commitment was received as of 12/31/2019.

## 7.6. Commitments towards employees

### 7.6.1. Retirement commitments

For estimated retirement commitments, the following assumptions were used for all categories of employees (employees, ETAM [Employees, Technicians, and Supervisors], and managers):

- retirement age: 65;
- terms of retirement: voluntary retirement;
- mortality table: INSEE 2018;
- collective agreement: metal industries;
- turnover: 24% for all employees;
- employer's contribution rate used: 47% vs 48% for last year;
- salary increase rate: 2% (same as in 2018).

discount rate: 1.17% (vs 1.97% in 2018) equal to the iBoxx Corporate AA10+ rate.

Retirement benefits stand at €234 thousand at the end of the 2019 financial year and are not recorded in the Company's financial statements.

The Company does not finance its pension plan provision. No retirements took place over the last two financial years.

**Financial statement for the financial year ended December 31, 2018**

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2018 are included for reference in this Universal Registration Document.

**Company financial statements for the year ended December 31, 2017**

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2017 as presented in the 2017 annual financial report are included for reference in this Universal Registration Document.

**Examination of the financial statement and results**

The financial statements for the year ended December 31, 2019, which we submit for your approval, have been drawn up in accordance with the rules of presentation and valuation methods pursuant to current legislation.

**Income statement**

Net revenues amounted to €6,632,371 compared with €8,338,447 for the previous financial year, representing a decrease of 20%.

Operating revenues were stable and totaled €8,099,198 versus €8,374,736 for the previous financial year. In 2019, these revenues included a reversal of the provision on trade receivables of €1,057 thousand recorded as a loss during the year.

Operating expenses amounted to €16,199,926 versus €15,431,172 for the previous financial year, representing an increase of 5%, and consisted of the following items:

| | |
|---|---|
| - Purchases of merchandise: | €0 |
| - Change in inventories: | €0 |
| - Purchases of raw materials and other supplies: | €1,351,633 |
| - Change in inventories: | €(171,565) |
| - Other purchases and external charges: | €6,298,484 |
| - Taxes: | €173,768 |
| -Wages and salaries: | €4,821,421 |
| - Social security expenses: | €2,210,751 |
| - Depreciation, amortization and provisions: | €283,326 |
| - Impairment allowances: | €128,024 |
| - Other expenses: | €1,104,084 |

The operating result was €(8,100,728) compared with €(7,056,436) for the previous financial year.

Our financial revenue and expenses amounted to €532,331 and €8,968.075 respectively, representing a net financial loss of €(8,435,744), compared with €(8,435,744) for the previous financial year. This decrease is mainly due to the impairment of the current account of the US subsidiary in the amount of €6,285,388.

Consequently the profit before tax stood at €(16,536,472) compared with €(13,014,930) for the previous financial year.

Non-recurring income stood at a loss of €(75,641) compared with a gain of €2,740 for the previous financial year.

After taking into account the Research Tax Credit of €997,342 and other tax credits amounting to €80,000, the result for the year is a loss of €(15,534,771) compared with €(11,871,126) for 2018.

Balance sheet

**Assets**

Intangible assets amounted to a net €266,531.

Property, plant and equipment amounted to a net €676,960.

Financial assets as of December 31, 2019 stood at the net amount of €4,460,848.

Current assets stood at a net €16,187,950 and prepaid expenses came to €132,599.

**Liabilities**

Share capital stood at €1,222,870 at December 31, 2019 versus €1,008,053 at the end of the previous financial year, and share premiums totalled €98,256,551 as of December 31, 2019 after the reserved capital increase subscribed to by Johnson & Johnson Innovation Inc.

Other reserves amounted to €(53,860) at December 31, 2019.

Accumulated losses amounted to €(86,657,811) as of December 31, 2019.

**Company's indebtedness position with regard to the volume and complexity of its business**

Liabilities amounted to €15,888,791 (compared with €7,952,677 at the end of the previous financial year), consisting mainly of:

| | |
|---|---|
| - the EIB loan: | €11,782,708 |
| -miscellaneous borrowings: | €11,312 |
| - trade payables: | €2,272,799 |
| - tax and employee-related liabilities: | €1,639,698 |
| - other payables: | €36,691 |
| - deferred revenues: | €145,584 |

In accordance with article L. 441-6-1 of the French Commercial Code, we point out that trade receivables totaling €2,230,862 (versus €2,001,982 the previous year) and trade and customer payables totaling €2,272,799 (versus €2,023,248 the previous financial year) break down by due date as follows:

**INVOICES RECEIVED AND UNPAID ON THE REPORTING DATE WHICH ARE DUE**

| | Article D. 441 I-1°: invoices received and unpaid on the reporting date which are due | | | | | | Article D. 441 I-2°: invoices issued and unpaid at the reporting date which are due | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 days | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91 days and over | Total (1 day and over) | 0 days | 1 to 30 days | 31 to 60 days | 61 to 90 days | 91 days and over | Total (1 day and over) |
| (A) Payment default tranches | | | | | | | | | | | | |
| Number of invoices concerned | 92 | | | | | 111 | 18 | | | | | 24 |
| Total amount of invoices concerned incl. tax (payables and receivables) (in €K) | 358 | 887 | 95 | 9 | 19 | 1,010 | 1367 | 43 | 18 | 462 | 866 | 1,389 |
| Percentage of total amount of purchases (excl. tax) in the financial year | 4.7% | 11.6% | 1.2% | 0.1% | 0.2% | 13.2% | | | | | | |
| Percentage of sales (excl. tax) in the financial year | | | | | | | 20.6% | 0.6% | 0.3% | 7.0% | 13.0% | 20.9% |
| (B) Invoices omitted from (A) relating to doubtful or unrecognized receivables and payables | | | | | | | | | | | | |
| No. of invoices omitted | 0 | | | | | | 0 | | | | | |
| Total amount of invoices omitted | 0 | | | | | | 0 | | | | | |
| (C) Reference payment terms used (contractual or legal – Article L. 441-6 or Article L. 443-1 of the French Commercial Code) | | | | | | | | | | | | |
| Payment terms used to calculate payment default | ■Contractual terms: payment on the 15th or 30th day of the month after the due date indicated by the suppliers<br>□ Legal terms | | | | | | ■Contractual terms<br>□ Legal terms | | | | | |

**Non-Tax-deductible expenses**

In application of Article 223 quater of the French General Tax Code, we ask you to approve the sumptuary expenses and non-deductible expenses referred to in Article 39-4 of this Code, which amount to €8,543.

**Table of results for the past five financial years**

| Type of indication / period | 12/31/2019 | 12/31/2018 | 12/31/2017 | 12/31/2016 | 12/31/2015 |
|---|---|---|---|---|---|
| Duration of the financial year | 12 months | 12 months | 12 months | 12 months | 12 months |
| I- Financial position at year-end | | | | | |
| a) Share capital | 1,222,870 | 1,008,053 | 973,893 | 800,074 | 647,068 |
| b) Number of shares issued | 5,357,142 | | | | |
| c) Number of bonds convertible into shares | | | | | |
| II - Comprehensive income from operations | | | | | |
| a) Sales excluding taxes | 6,632,371 | 8,338,447 | 6,287,244 | 7,331,438 | 7,368,575 |
| b) Profit/(loss) before tax, depreciation, amortization and provisions | -10,965,379 | -6,786,079 | -6,652,102 | -6,335,344 | -8,169,270 |
| c) Income tax | -1,077,342 | -1,141,064 | -1,144,487 | -863,631 | -1,264,596 |
| d) Profit/(loss) after tax, but before depreciation, amortization and provisions | -9,888,037 | -5,645,015 | -5,507,615 | -5,491,713 | -6,904,674 |
| e) Profit/(loss) after tax, depreciation, amortization and provisions | -15,534,771 | -11,871,126 | -3,982,199 | -10,610,123 | -15,424,674 |
| f) Amount of profits distributed | | | | | |
| g) Employee shareholding | | | | | |
| III - Earnings per share | | | | | |
| a) Profit/(loss) after tax, but before depreciation and amortization | | | | | |
| b) Profit/(loss) after tax, depreciation, amortization and provisions | | | | | |
| c) Dividends paid per share | | | | | |
| IV - Employees: | | | | | |
| a) Number of employees | 75 | 74 | 71 | 62 | 72 |
| b) Total payroll | 4,821,421 | 4,888,217 | 4,572,162 | 4,664,788 | 5,959,220 |
| c) Total amounts paid in relation to employee benefits | 2,210,751 | 2,143,104 | 2,005,466 | 2,069,015 | 2,546,525 |

## 20.3 Pro forma financial information

Not applicable.

## 20.4 Historical financial statements of Mauna Kea Technologies SA

See Section 20.2

## 20.5 Verification of annual historical financial information

**Statutory auditors' report on the consolidated financial statements prepared according to IFRS standards as adopted in the European Union for the financial years ended December 31, 2019**

**EXCO SOCODEC**
51, avenue Françoise Giroud
21000 Dijon
S.A.R.L. au capital de € 3 200 000
400 726 048 R.C.S. Dijon

Commissaire aux Comptes
Membre de la compagnie
régionale de Dijon

**ERNST & YOUNG et Autres**
Tour First
TSA 14444
92037 Paris-La Défense cedex
S.A.S. à capital variable
438 476 913 R.C.S. Nanterre

Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

### Mauna Kea Technologies

Year ended December 31, 2019

**Statutory auditors' report on the consolidated financial statements**

To the Annual General Meeting of Mauna Kea Technologies,

#### Opinion

In compliance with the engagement entrusted to us by your Annual General Meetings, we have audited the accompanying consolidated financial statements of Mauna Kea Technologies for the year ended December 31, 2019. These consolidated financial statements were approved by the Board of Directors, on April 27, 2020, on the basis of the elements available at that date, in the evolving context of the health crisis related to Covid-19.

In our opinion, the consolidated financial statements give a true and fair view of the assets and liabilities and of the financial position of the Group as at December 31, 2019 and of the results of its operations for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

The audit opinion expressed above is consistent with our report to the Audit Committee.

## Basis for Opinion

### Audit Framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the *Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements* section of our report.

### Independence

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2019 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No. 537/2014 or in the French Code of Ethics *(Code de déontologie)* for statutory auditors.

## Emphasis of Matter

We draw attention to the following matter described in Note 1.1 to the consolidated financial statements relating to the application of IFRS16 "Lease contracts". Our opinion is not modified in respect of this matter.

## Justification of Assessments - Key Audit Matters

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code *(Code de commerce)* relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the consolidated financial statements as a whole, as approved in the above-mentioned context, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the consolidated financial statements.

■ **Revenue recognition**

| Risk identified | Our responses |
|---|---|
| Sales of the group's products and services are under the terms described in Note 15 to the consolidated financial statements.<br><br>The Company's revenue is mainly the result of the sale of systems, the sale of consumables (soundings) and maintenance services and repair.<br><br>For product sales, sales are found as soon as the transfer of ownership is carried out.<br><br>We considered that the recognition of the revenue is a key audit matter considered the weight given to the turnover as a financial indicator of the group and the importance of transactions unwind as year-end approaches. | We analyzed the methods of the revenue recognition and controls set up by the Company. Our work included:<br><br>► examining contractual clauses on a sample contracts, including the most significant contract of the financial year, in order to analyze the applicable accountant treatment;<br><br>► examining the most significant transactions of the financial year, by getting the orders, invoices, delivery notes or availability vouchers, as well as significant transactions with new customers or in countries where the Company has a reduced business;<br><br>► performing sampling tests in order to confirm the correct application of the principle of separation of financial years on a selection of significant transactions accounted before and after the closing date to determine whether these products are related to the appropriate period. |

## Specific verifications

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations of the information relating to the Group given in the Board of Directors' management report, as approved on April 27, 2020. Regarding the events that occurred and the elements known after the date of approval of the consolidated financial statements relating to the effects of the Covid-19 crisis, Management has informed us that such events and elements will be communicated to the Annual General Meeting called to decide on these financial statements.

We have no matters to report as to their fair presentation and their consistency with the consolidated financial statements.

## Report on Other Legal and Regulatory Requirements

■ **Appointment of the Statutory Auditors**

We were appointed as statutory auditors of Mauna Kea Technologies by your Annual General Meeting held on June 13, 2018 for EXCO SOCODEC and on May 25, 2011 for ERNST & YOUNG et Autres.

As at December 31, 2019, EXCO SOCODEC was in the second-year and ERNST & YOUNG et Autres in the ninth year of uninterrupted engagement.

## Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as adopted by the European Union and for such internal control as Management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, Management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The consolidated financial statements were approved by the Board of Directors.

## Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

### Objectives and audit approach

Our role is to issue a report on the consolidated financial statements. Our objective is to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As specified in Article L.823-10-1 of the French Commercial Code (*Code de commerce*), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management in the consolidated financial statements.

- Assesses the appropriateness of Management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the consolidated financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.

- Evaluates the overall presentation of the consolidated financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtains sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. The statutory auditor is responsible for the direction, supervision and performance of the audit of the consolidated financial statements and for the opinion expressed on these consolidated financial statements.

## Report to the Audit Committee

We submit to the Audit Committee a report which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the consolidated financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) No. 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code *(Code de commerce)* and in the French Code of Ethics *(code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Dijon and Paris-La Défense, April 29, 2020

The Statutory Auditors
*French original signed by*

EXCO SOCODEC — ERNST & YOUNG et Autres

Olivier Gallezot — Cédric Garcia

**Statutory auditors' report on the annual financial statements for financial years ended December 31, 2019**

**EXCO SOCODEC**
51, avenue Françoise Giroud
21000 Dijon
S.A.R.L. au capital de € 3 200 000
400 726 048 R.C.S. Dijon

Commissaire aux Comptes
Membre de la compagnie
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Commissaire aux Comptes
Membre de la compagnie
régionale de Versailles

## Mauna Kea Technologies

Year ended December 31, 2019

**Statutory auditors' report on the financial statements**

To the Annual General Meeting of Mauna Kea Technologies,

### Opinion

In compliance with the engagement entrusted to us by your Annual General Meetings, we have audited the accompanying financial statements of Mauna Kea Technologies for the year ended December 31, 2019. These financial statements were approved by the Board of Directors, on April 27, 2020, on the basis of the elements available at that date, in the evolving context of the health crisis related to Covid-19.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company as at December 31, 2019 and of the results of its operations for the year then ended in accordance with French accounting principles.

The audit opinion expressed above is consistent with our report to the Audit Committee.

### Basis for Opinion

- **Audit Framework**

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the *Statutory Auditors' Responsibilities for the Audit of the Financial Statements* section of our report.

- **Independence**

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2019 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No. 537/2014 or in the French Code of Ethics *(Code de déontologie)* for statutory auditors.

## Justification of Assessments

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code *(Code de commerce)* relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the financial statements as a whole, as approved in the above-mentioned context, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

- **Revenue recognition**

| Risk identified | Our response |
|---|---|
| Sales of the Company's products and services are recognized under the terms described in Note 3.9 to the financial statements.<br><br>The Company's revenue is mainly the result of the sale of systems, the sale of consumables (soundings) and maintenance services and repair.<br><br>For product sales, sales are found as soon as the transfer of ownership is carried out.<br><br>We considered that the recognition of the revenue is a key audit matter considering the weight given to the turnover as a financial indicator of the group and the importance of transactions unwind as year-end approaches. | We analyzed the methods of the revenue recognition and controls set out by the Company. Our work included:<br><br>► examining the contractual clauses on a sample contracts, including the most significant financial year, in order to analyze the applicable accountant treatment;<br><br>► examining the most significant transactions of the financial year, by getting the orders, invoices, delivery notes or availability vouchers, as well as significant transactions with new customers or in countries where the Company has a reduced business;<br><br>► Performing sampling tests in order to confirm the correct application of the principle of separation of financial years on a selection of significant transactions accounted for before and after the closing date to determine whether these products are related to the appropriate period. |

## Specific verifications

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations.

- **Information given in the management report and in the other documents with respect to the financial position and the financial statements provided to the shareholders**

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in the Board of Directors' management report, as approved on April 27, 2020, and in the other documents with respect to the financial position and the financial statements provided to the shareholders. Regarding the events that occurred and the elements known after the date of approval of the financial statements relating to the effects of the Covid-19 crisis, Management has informed us that such events and elements will be communicated to the Annual General Meeting called to decide on these financial statements.

We attest the fair presentation and the consistency with the financial statements of the information relating to payment deadlines mentioned in Article D. 441-4 of the French Commercial Code (*Code de commerce*).

- **Report on Corporate Governance**

We attest that the Board of Directors' Report on Corporate Governance sets out the information required by Articles L. 225-37-3 and L. 225-37-4 of the French Commercial Code (*Code de commerce*).

Concerning the information given in accordance with the requirements of Article L. 225-37-3 of the French Commercial Code *(Code de commerce)* relating to remunerations and benefits received by, or allocated to the directors and any other commitments made in their favor, we have verified its consistency with the financial statements, or with the underlying information used to prepare these financial statements and, where applicable, with the information obtained by your Company from companies controlled thereby, included in the consolidation scope. Based on these procedures, we attest the accuracy and fair presentation of this information.

Regarding information relating to items your company considered likely to have an impact on the event of a takeover or exchange offer, in accordance with the requirements of Article L. 225-37-5 of the French Commercial Code, we verified their compliance with the documents from which they came and which were provided to us. On the basis of this work, we have no comment on this information.

- **Other information**

In accordance with French law, we have verified that the required information concerning the purchase of investments and controlling interests and the identity of the shareholders and holders of the voting rights has been properly disclosed in the management report.

## Report on Other Legal and Regulatory Requirements

We were appointed as statutory auditors of Mauna Kea Technologies by the general meeting held on June 13, 2018 for EXCO SOCODEC and on May 25, 2011 for ERNST & YOUNG et Autres.

As at December 31, 2019, EXCO SOCODEC was in the second-year and ERNST & YOUNG et Autres in the ninth year of uninterrupted engagement.

## Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with French accounting principles and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The financial statements were approved by the Board of Directors.

## Statutory Auditors' Responsibilities for the Audit of the Financial Statements

### Objectives and audit approach

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As specified in Article L. 823-10-1 of the French Commercial Code *(Code de commerce)*, our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.
- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the financial statements.
- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.
- Evaluates the overall presentation of the financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

### Report to the Audit Committee

We submit to the Audit Committee a report which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the consolidated financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) No. 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code *(Code de commerce)* and in the French Code of Ethics *(code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Dijon and Paris-La Défense, April 29, 2020

The Statutory Auditors
*French original signed by*

EXCO SOCODEC — ERNST & YOUNG et Autres

Olivier Gallezot — Cédric Garcia

## 20.6 Date of most recent financial information

December 31, 2019

## 20.7 Consolidated interim financial information

Not applicable.

## 20.8 Dividend distribution policy

### 20.8.1 Dividends paid during the last three financial years

N/A.

### 20.8.2 Dividend distribution policy

There are no plans to initiate a dividend payment policy in the near term in view of the Company's stage of development.

## 20.9 Legal and arbitration proceedings

As of the filing date of the Universal Registration Document, there are no government, legal or arbitration proceedings to the Company's knowledge that are pending or threatened and likely to have a material impact on the financial position, operations or earnings of the Company and/or its subsidiary in the last 12 months.

No unfunded litigation currently exists.

As of December 31, 2019, no new labor dispute was reported.

## 20.10 Significant change to financial or commercial position

As far as the Company is aware, there has been no significant change in the Group's financial or commercial position since December 31, 2019.

# SECTION 21
# 21. ADDITIONAL INFORMATION

## 21.1 Share capital

### 21.1.1 Securities not representing capital

**Amount of share capital**

At December 31, 2019, the Company's share capital totaled €1,222,869.60 divided into 30,571,740 shares with a par value of €0.04 each, fully paid up.

### 21.1.2 Securities not representing capital

N/A.

### 21.1.3 Company's buyback of its own shares

- **Share buyback program adopted at the Company's Ordinary General Meeting on July 5, 2019**

In accordance with the provisions of Article L. 233-13 of the French Commercial Code and taking into account the information received pursuant to Articles L. 233-7 and L. 233-12 of said Code, we inform you that Johnson & Johnson Innovation Inc. directly held more than 5%, 10% and 15% of the share capital or voting rights at the Company's Annual General Meetings on December 31, 2019.

No other shareholder held either directly or indirectly more than 5%, 10%, 15%, 20%, 25%, 33.33%, 50%, 66.67%, 90% and 95% of the share capital or voting rights at the Company's Annual General Meetings on December 31, 2019.

By virtue of the contract agreed with Gilbert Dupont on July 5, 2019, the Company held 35,786 shares representing 0.12% of its share capital at December 31, 2019. At this date, the portfolio value was €59,484.61, based on the closing price at December 31, 2019, i.e. €1.37.

These shares, valued based on the FIFO method, were acquired based on a carrying amount of €48,882.43.

During the financial year 2019 under this contract, 1,095,866 shares were bought at an average price of €1.48 and 1,098,899 shares were sold at an average price of €1.47.

The Company did not buy back its Treasury shares for other reasons.

The Company has not informed any other limited liability company that it holds more than 10% of its capital. The Company has no cross-holdings and has not therefore disposed of any shares.

Summary of transactions performed by the Company on its own securities between January 1, 2019 and December 31, 2019:

| | 2019 | | | | |
|---|---|---|---|---|---|
| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter | Total |
| Securities purchased | 188 271 | 160 904 | 387 291 | 359 400 | 1 095 866 |
| Price | 2,02 | 1,67 | 1,57 | 1,02 | |
| Total amount (in K€) | 381 | 268 | 608 | 367 | 1 624 |
| Securities sold | 173 316 | 169 636 | 366 040 | 389 907 | 1 098 899 |
| Price | 2,05 | 1,69 | 1,58 | 1,02 | |
| Total amount (in K€) | 356 | 286 | 579 | 399 | 1 620 |

Features of the Company's share buyback program:

The Extraordinary General Meeting of July 5, 2019, authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with the provisions of Article L. 225-209 et seq. of the French Commercial Code and in accordance with the General Regulation of the Autorité des Marchés Financiers (AMF) under the terms and conditions described below:

**Objectives of the share buyback program**:

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be concluded with an investment services provider, in accordance with a Code of Conduct approved by the AMF;
- to honor obligations linked to stock option and bonus share plans;
- company savings schemes or other share awards to employees and executives of the Company or its associates;
- to deliver shares when the rights attached to securities giving access to the share capital are exercised;
- to purchase shares to be held for their subsequent exchange or use as consideration in potential acquisitions;
- or to cancel some or all of the shares thus repurchased.

**Maximum purchase price**: €30 per share excluding fees and commissions, with a total limit of €5,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

The shares purchased in this way may be canceled.

- **Share buyback program adopted at the Company's Combined General Meeting on July 2, 2020**

The Combined General Meeting of July 2, 2020, authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with the provisions of Article L. 225-209 et seq. of the French Commercial Code and in accordance with the General Regulation of the Autorité des Marchés Financiers (AMF) under the terms and conditions described below. This program took the place of the program adopted at the Ordinary General Meeting of July 5, 2019.

**Objectives of the share buyback program:**

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be concluded with an investment services provider, in accordance with an ethics charter approved by the AMF; and/or
- to honor obligations linked to stock option and bonus share plans;
- company savings schemes or other share awards to employees and executives of the Company or its associates; and/or
- to tender shares upon exercise of the rights attached to securities giving access to the share capital; and/or
- to purchase shares to be held for their subsequent exchange or use as consideration in potential acquisitions in compliance with market practices permitted by the AMF; and/or
- in general, to conduct transactions for any purpose that may be authorized by law or any market practice that may be permitted by the market authorities, it being specified that, in such a situation, the Company would inform its shareholders through a press release.

**Maximum purchase price:** €5 per share, excluding fees and commissions (this purchase price will be adjusted to take account of capital transactions, in particular in the capitalization of reserves, bonus share grants, stock splits or reverse stock splits), with an overall ceiling of €4,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

The number of shares acquired by the Company to be held and subsequently exchanged or used as consideration for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of the total number of shares.

**Buyback methods**: the acquisition, sale or transfer of shares may be carried out by any means, on one or more occasions, in particular on the market or over-the-counter, including by block purchases or sales, public offers, using options or derivative mechanisms, under the conditions pursuant to the market authorities and in compliance with applicable regulations.

#### 21.1.4 Financial instruments giving access to the capital

Four different types of securities give access to the capital:

- Founders' warrants (BSPCE);
- Stock options (SO);
- Share warrants (BSA);
- Preference shares (AP).

| Plan no. | | BSPCE 10 | | BSPCE 11 | BSPCE 12 & 13 | | BSPCE 14 |
|---|---|---|---|---|---|---|---|
| Date of General Meeting | 05/27/08 and 06/16/09 | 06/30/10 | | 05/25/11 | 06/15/12 | | 06/19/13 |
| Date of Chairman's decisions | 11/24/09 | 02/15/11 | 03/01/11 | 12/05/11 | 12/04/12 | 05/07/13 | 02/12/14 |
| Number of BSPCE authorized (1) | 1 900 000 | 1 250 000 | 1 250 000 | 800 000 | 800 000 | 800 000 | 800 000 |
| Total number of BSPCE granted (1) | 637 500 | 915 000 | 200 000 | 129 500 | 239 500 | 63 000 | 281 000 |
| Total number of shares that may initially be subscribed for (2) | 637 500 | 915 000 | 200 000 | 129 500 | 239 500 | 63 000 | 281 000 |
| of which the number that may be subscribed by corporate officers: | | | | | | | |
| *Alexandre LOISEAU* | *0* | *0* | *0* | *0* | *0* | *0* | *100 000* |
| Number of beneficiaries who are not corporate officers | 21 | 27 | 1 | 13 | 46 | 7 | 42 |
| Start date for exercise of the BSPCE | 11/24/10 | 02/15/12 | 03/01/12 | 12/05/12 | 12/04/13 | 05/07/14 | 02/12/15 |
| BSPCE expiration date | 11/24/19 | 02/15/21 | 03/01/21 | 12/05/21 | 12/04/22 | 05/07/23 | 02/12/24 |
| BPSCE exercise price (3) | 4,00 € | 4,00 € | 4,00 € | 13,00 € | 10,79 € | 10,28 € | 10,56 € |
| Exercise procedures | (4) | (4) | (4) | (4) | (4) | (4) | (4) |
| Number of shares subscribed at December 31, 2019 (3) | 38 748 | 79 562 | 37 500 | 0 | 625 | 0 | 0 |
| Cumulative number of BSPCE canceled or invalid as at December 31, 2019 (1) | 482 508 | 506 752 | 0 | 117 000 | 205 875 | 36 000 | 125 000 |
| BSPCE remaining at December 31, 2019 (1) | 0 | 90 000 | 50 000 | 12 500 | 33 000 | 27 000 | 156 000 |
| Total number of shares that may be subscribed for at December 31, 2019 (3) | 0 | 22 500 | 12 500 | 12 500 | 33 000 | 27 000 | 156 000 |

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 had no impact on the number of BSPCE issued, void, canceled or remaining. Only their exercise conditions are adjusted (price and parity). It should be noted that the last column of the table specifies a BSPCE plan itself allocated after the 4-for-1 reverse stock split decision. The initial characteristics mentioned in the table therefore already take the 4-for-1 reverse stock split into account;
(2) The conditions for exercising the BSPCE have been adjusted to account for the 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011. This line corresponds to a figure calculated before taking said reverse stock split into account, i.e. an exercise parity of one new share per exercise of one BSPCE. Plans since May 25, 2011 have a parity of one new share for every BPSCE.
(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 resulted in the adjustment of only the exercise price and parity of the BSPCE and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account, except for those in the last column, since the detailed plan was allocated after the 4-for-1 reverse stock split decision. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.
(4) As the conditions provided fat the time of their allocation are waived, all the BSPCE may be exercised.
The procedures for exercising the BSPCE are as follows:
25% of the BSPCE may be exercised starting on the first anniversary of their allocation;
25% of the BSPCE may be exercised starting on the second anniversary of their allocation;
25% of the BSPCE may be exercised starting on the third anniversary of their allocation;
the remaining balance, i.e., 25% of the BSPCE, may be exercised starting on the fourth anniversary of their award.
As of December 31, 2019, the exercise of all BSPCE could lead to the creation of 285,063 new ordinary shares after taking into account the 4-for-1 reverse stock split, potentially exercisable or not on the date of this report under the conditions set out in this section.

**Stock Option Plans**

| Information on the Stock Option Plans | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Date of General Meeting | 05/27/08 | 06/30/10 | 05/27/15 | 05/27/15 | 05/27/15 | 05/03/17 | 05/03/17 | 05/03/17 | 05/03/17 | 10/05/18 | 10/05/18 | 10/05/18 | 10/05/18 | 07/05/19 | 07/05/19 |
| Date of Chairman's decisions | 03/01/10 | 01/31/11 | 02/02/16 | 07/26/16 | 03/21/17 | 07/19/17 | 02/28/18 | 07/24/18 | 09/19/18 | 11/12/18 | 11/28/18 | 02/07/19 | 05/19/19 | 07/31/19 | 11/20/19 |
| Total number of options authorized | 960 000 | 750 000 | 400 000 | 400 000 | 400 000 | 400 000 | 400 000 | 400 000 | 400 000 | 750 000 | 750 000 | 750 000 | 750 000 | 500 000 | 500 000 |
| Total number of options granted (1) | 250 000 | 245 000 | 96 000 | 80 000 | 60 000 | 154 000 | 300 000 | 80 000 | 40 000 | 600 000 | 35 000 | 40 000 | 75 000 | 127 500 | 55 000 |
| Total number of shares that may initially be subscribed for (2)<br>*of which the number that may be subscribed by corporate officer* | 250 000<br>*0* | 245 000<br>*0* | 96 000<br>*0* | 80 000<br>*0* | 60 000<br>*0* | 154 000<br>*0* | 300 000<br>*0* | 80 000<br>*0* | 40 000<br>*0* | 600 000<br>*1* | 35 000<br>*0* | 40 000<br>*0* | 75 000<br>*0* | 127 500<br>*0* | 55 000<br>*0* |
| Number of beneficiaries who are not corporate officers | 3 | 5 | 10 | 2 | 1 | 12 | 14 | 2 | 4 | 0 | 4 | 1 | 3 | 2 | 1 |
| Start date for exercise of the options | 03/01/10 | 01/31/12 | 02/02/17 | 07/26/17 | 03/21/18 | 07/19/18 | 02/28/19 | 07/24/19 | 09/19/19 | 11/12/19 | 11/28/19 | 12/07/20 | 05/18/20 | 07/30/20 | 11/19/20 |
| Option expiration date | 03/01/20 | 01/31/21 | 02/02/26 | 07/26/26 | 03/21/27 | 07/19/27 | 02/28/28 | 07/24/28 | 09/19/28 | 11/12/28 | 11/28/28 | 02/07/29 | 05/19/19 | 07/31/29 | 11/20/29 |
| Subscription price (3) | 4,00 € | 4,00 € | 2,54 € | 1,60 € | 2,92 € | 2,34 € | 3,12 € | 2,54 € | 2,86 € | 2,59 € | 2,52 € | 2,13 € | 1,63 € | 1,67 € | 0,86 € |
| Exercise procedures | (4) | (4) | (5) | (5) | (5) | (6) | (6) | (6) | (6) | (6) | (6) | (6) | (6) | (6) | (6) |
| Number of shares subscribed at December 31, 2019 (3) | 2 500 | 14 062 | 10 500 | 10 000 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of stock options canceled or invalid (1) | 100 000 | 128 752 | 85 500 | 0 | 60 000 | 119 000 | 195 000 | 40 000 | 0 | 0 | 0 | 0 | 0 | 50 000 | 0 |
| Stock options remaining at December 31, 2019 (1) | 140 000 | 60 000 | 0 | 70 000 | 0 | 35 000 | 105 000 | 40 000 | 40 000 | 600 000 | 35 000 | 40 000 | 75 000 | 77 500 | 55 000 |
| Number of shares that may be subscribed for as of December 31, 2019 (3) | 35 000 | 15 000 | 0 | 50 000 | 0 | 21 000 | 21 000 | 8 000 | 8 000 | 120 000 | 7 000 | 0 | 0 | 0 | 0 |

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 had no impact on the number of stock options granted, canceled, void or remaining. Only their exercise conditions are adjusted (price and parity).

(2) The conditions for exercising the stock options have been adjusted to account for the 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011. This line corresponds to a figure calculated before taking said reverse stock split into account, i.e. an exercise parity of one new share for every stock option exercised.

(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 resulted in the adjustment of only the exercise price and parity of the stock options and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.

(4) As the conditions provided fat the time of their allocation are waived, all the stock options may be exercised.

(5) The methods for exercising stock options (S.O.) are as follows:
- 25% of the S.O. may be exercised starting on the first anniversary of their allocation;
- 25% of additional S.O. may be exercised starting on the second anniversary of their allocation;
- 25% of additional S.O. may be exercised starting on the third anniversary of their allocation;
- the remaining balance, i.e. 25% of the S.O., may be exercised from the fourth anniversary of their allocation.

(6) The methods for exercising stock options (S.O.) are as follows:
- 20% of the S.O. may be exercised starting on the first anniversary of their allocation;
- 40% of additional S.O. may be exercised starting on the second anniversary of their allocation;
- 250% of additional S.O. may be exercised starting on the third anniversary of their allocation;
- the remaining balance, i.e. 20% of the S.O., may be exercised from the fourth anniversary of their allocation.

As of December 31, 2019, the exercise of all stock options granted could lead to the creation of 321,750 new ordinary shares, potentially exercisable or not as of the date of this report under the conditions set forth in paragraph (5) and (6).

**Share Warrant (BSA) Plan**

| | BSA 2014 | BSA 2016 | BSA 2017-2 | BSA 2018 | BSA 2018 | BSA 2019 | BSA 2019 | BSA 2020 |
|---|---|---|---|---|---|---|---|---|
| Date of General Meeting | 07/11/14 | 05/04/16 | 05/03/17 | 05/03/17 | 10/05/18 | 10/05/18 | 07/05/18 | 07/02/20 |
| Date of Chairman's decisions | 09/01/14 | 07/26/16 | 12/01/17 | 02/28/18 | 11/12/18 | 05/19/19 | 07/02/19 | 07/07/20 |
| Number of authorized share warrants (BSA) | 400 000 | 400 000 | - | 400 000 | 400 000 | 400 000 | - | - |
| Total number of BSA issued (1) | 160 000 | 115 000 | 2 250 000 | 55 000 | 40 000 | 170 000 | 1 450 000 | 500 000 |
| Total number of shares that may initially be subscribed for (2) | 160 000 | 115 000 | 2 250 000 | 55 000 | 40 000 | 170 000 | 1 450 000 | 500 000 |
| of which the number that may be subscribed by corporate officers: | 120 000 | 115 000 | 0 | 55 000 | 0 | 170 000 | 0 | 0 |
| *André Michel Ballester* | *30 000* | | | | | | | |
| *Christopher Mc Fadden* | *30 000* | *40 000* | | | *40 000* | *50 000* | | |
| *Jean-Luc Boulnois* | *30 000* | *25 000* | | | | | | |
| *Joseph Devivo* | | *25 000* | | | | *40 000* | | |
| *Marie Meynadier* | *30 000* | *25 000* | | | | | | |
| *Jennifer Tseng* | | | | *30 000* | | *40 000* | | |
| *Molly O'Neill* | | | | *25 000* | | *40 000* | | |
| Number of beneficiaries who are not corporate officers | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 1 |
| Start date for exercise of the BSA | 09/01/15 | 07/26/17 | 12/01/17 | 02/28/19 | 11/12/19 | 05/19/20 | 07/03/19 | 07/08/20 |
| BSA expiration date | 09/01/24 | 07/26/26 | 12/01/19 | 02/28/28 | 11/12/28 | 05/19/29 | 07/02/39 | 07/02/39 |
| BSA issue price | 0,61 € | 0,16 € | | 0,30 € | 0,28 € | 0,17 € | 0,01 € | 0,01 € |
| BSA exercise price (3) | 6,12 € | 1,68 € | (5) | 3,12 € | 2,76 € | 1,84 € | 1,8856 € | 1,2403 € |
| Exercise procedures | (4) | (4) | (5) | (4) | (4) | (4) | (5) | (5) |
| Number of shares subscribed at December 31, 2019 (3) | 0 | 0 | 2 050 000 | 0 | 0 | 0 | 0 | 0 |
| Cumulative number of BSA canceled or invalid as of December 31, 2019 (1) | 60 000 | 33 333 | 0 | 0 | 0 | 0 | 0 | 0 |
| BSA remaining at December 31, 2019 (1) | 100 000 | 81 667 | 200 000 | 55 000 | 40 000 | 170 000 | 1 450 000 | 500 000 |
| Number of shares that may be subscribed for as of December 31, 2019 (3) | 100 000 | 81 667 | 200 000 | 18 333 | 13 333 | 170 000 | 1 450 000 | 500 000 |

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 had no impact on the number of BSA authorized, issued, void, canceled or remaining. Only their exercise conditions are adjusted (price and parity).

(2) The conditions for exercising the BSA have been adjusted to account for the 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011. This line corresponds to a figure calculated before taking said reverse stock split into account, i.e. an exercise parity of one new share for every BSA exercised.

(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 resulted in the adjustment of only the exercise price and parity of the BSA and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.

(4) One-third of BSA may be exercised after a period of 12 months, and then in additional one-third tranches at the end of each year for two years, subject to a 75% attendance rate at board meetings held in each of the three years.

(5) BSA: see Section 10.1of this Universal Registration Document.

At December 31, 2019, the exercise of all BSA granted, potentially exercisable or not at the date of this report under the conditions set forth in paragraph (4), could lead to the creation of 421,667 new ordinary shares.

**Preference shares (AP)**

| Information relating to the preference shares | | | | | | | |
|---|---|---|---|---|---|---|---|
| Date of General Meeting | 05/04/16 | 05/04/16 | 05/04/16 | 10/05/18 | 10/05/18 | 10/05/18 | 10/05/18 |
| Date of Chairman's decisions | 07/26/16 | 11/15/16 | 10/17/17 | 10/10/18 | 11/12/18 | 09/19/19 | 11/20/19 |
| Total number of options authorized | 8 500 | 8 500 | 8 500 | 9 000 | 9 000 | 9 000 | 9 000 |
| Total number of options granted (1) | 7 765 | 570 | 2 340 | 5 700 | 1 375 | 150 | 400 |
| Total number of shares that may initially be subscribed for (2)<br>*of which the number that may be subscribed by corporate officers* | 7 765<br>*2 875* | 570<br>*0* | 2 340<br>*0* | 5 700<br>*4500* | 1 375<br>*0* | 150<br>*0* | 400<br>*0* |
| Number of beneficiaries who are not corporate officers | 62 | 4 | 4 | 1 | 21 | 1 | 1 |
| Start date for exercise of the options | 07/26/17 | 11/15/17 | 10/17/18 | 10/10/19 | 11/12/19 | 09/19/20 | 11/20/20 |
| Option expiration date | * | * | * | * | * | * | * |
| Subscription price | 2,53 | 3,15 | 2,87 | 0,99 | 0,93 | | |
| Exercise procedures | * | * | * | * | * | * | * |
| Number of shares subscribed at December 31, 2018 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of shares subscribed at December 31, 2018 | 5 915 | 220 | 350 | 5 700 | 1 075 | 0 | 0 |
| Cumulative number of canceled preference shares returned to the pool | 1 850 | 350 | 1 990 | 0 | 300 | 150 | 0 |
| Preference shares remaining at December 31, 2018 | 5 915 | 220 | 350 | 5 700 | 1 075 | 0 | 400 |
| Number of shares that may be subscribed for as of December 31, 2018 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total number of potential shares maximum if procedures are fullfilled (5) | 5 915 | 220 | 350 | 5 700 | 1 075 | 0 | 400 |

***The main characteristics are as follows:**

The Company may decide to convert the Preference Shares definitively acquired by the Beneficiaries on the Acquisition Date into new or existing ordinary shares ("Ordinary Shares") at any time from the third anniversary of the Acquisition Date (the period between the Allocation Date and said third anniversary (inclusive), known as the "Holding Period"), in accordance with the following:

a. in the event of the Beneficiary's Departure between the Acquisition Date (inclusive) and the first anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into twenty Ordinary Shares.

b. in the event of the Beneficiary's Departure between the first anniversary of the Acquisition Date (inclusive) and the second anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into thirty-three Ordinary Shares.

c. in the event of the Beneficiary's Departure between the second anniversary (inclusive) and the third anniversary (exclusive) of the Acquisition Date, the conversion ratio will be determined as follows:

(i) if the Benchmark Price 1 is strictly less than the Floor Price, each Preference Share shall be convertible into thirty-three Ordinary Shares;

(ii) if the Benchmark Price 1 is strictly higher than the Intermediate Price, each Preference Share shall be convertible into sixty-six Ordinary Shares;

(iii) if the Benchmark Price 1 is between the Floor Price (inclusive) and the Intermediate Price (inclusive), each Preferred Share shall carry entitlement to the following number of Ordinary Shares:

$33 + 33 \times [(\text{Benchmark Price 1} / \text{Floor Price}) - 1]$

where:

- the term "Acquisition Price" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 60 trading sessions preceding the Acquisition Date;
- the term "Floor Price" means the Acquisition Price plus two euros;
- the term "Intermediate Price" means the Minimum Price multiplied by two; and

- the term "Benchmark Price 1" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 120 trading sessions preceding the second anniversary of the Acquisition Date;

d. in the event of the Beneficiary's Departure after the Holding Period, each Preference Share shall carry entitlement to the following number of Ordinary Shares:

(x) of the number of Ordinary Shares calculated in accordance with the provisions of paragraph 3.c) above as if the Departure of the beneficiary had occurred between the second and the third anniversary of the Acquisition Date, and;

(y) of the following number of Ordinary Shares:

(i) if the Reference Price 2 is strictly lower than the Floor Price: none;

(ii) if the Benchmark Price 2 is strictly lower than the Ceiling Price: the difference between one hundred Ordinary Shares and the number of Ordinary Shares determined in (x) (such that the sum of (x) and (y) equals 100);

(iii) if the Reference Price 2 is between the Floor Price (included) and the Ceiling Price (included): the difference, if positive, between:

where:

- 33 + 67 × [(Benchmark Price 2 / Minimum Price) – 1] / 2;
- the number of Ordinary Shares determined under (x).

  - the term "Minimum Price" has the meaning assigned to it in paragraph 3.c) above;
  - the term "Ceiling Price" means the Minimum Price multiplied by three; and
  - the term "Benchmark Price 2" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 120 trading sessions preceding the third anniversary of the Acquisition Date. It should be noted that this conversion rate may be adjusted to take account of shares to be issued to protect the rights of holders of securities giving access to the Company's share capital, and the beneficiaries of Preference Shares, in accordance with applicable legal and regulatory provisions. The Preference Shares may be converted only during the period of five years and six months following the expiration of the Holding Period (the "Holding Period").

### 21.1.5 Authorized share capital

**Summary table of current delegations of authority and powers granted by the Annual General Meetings of October 5, 2018 and May 3, 2017 to the Board of Directors and the use made of these during the 2019 financial year**

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| **Combined General Meeting of May 3, 2017** | | | |
| May 3, 2017 (30th resolution) | Delegation of authority to be granted to the Board of Directors to issue and allocate share warrants to (i) members and non-voting members of the Board of Directors of the Company in office at the warrant allocation date and who are not employees or executives of the Company or of one of its subsidiaries, (ii) a service provider or consultant under contract to the Company or to one of its subsidiaries, or (iii) members of any committee that the Board of Directors should establish who are not employees or executives of the Company or of one of its subsidiaries.<br>(Articles L. 225-129 et seq. of the French Commercial Code, and in particular, Articles L. 225-129-2, L. 225-129-4, L. 225-135, L. 225-138 and L. 228-91 et seq. of the French Commercial Code)<br>Maximum number of share warrants: 400,000 | October 5, 2018<br>A delegation with the same purpose was granted by the General Meeting of October 5, 2018. | The Board meeting of February 28, 2018, making use of said delegation, decided to issue, at a unit price of €0.30, 55,000 share warrants (BSAs) to Directors of the Company each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €3.12 (including share premium).<br>The Board of Directors on March 22, 2018, making use of said delegation, decided to issue, at a unit price of €0.16, 50,000 share warrants (BSAs) to a service provider of the Company each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €2.92 (including share premium). |

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| | | | |
| **Extraordinary General Meeting of October 5, 2018** | | | |
| October 5, 2018 (8th resolution) | Delegation of authority granted to the Board of Directors to increase the share capital by issuing ordinary shares and/or any securities giving access to other equity securities or to the allocation of debt securities, and/or securities giving access to future equity securities, without preferential subscription rights for shareholders, for the benefit of a second category of persons meeting pre-determined criteria.<br>(Articles L. 225-129 et seq. of the French Commercial Code, and in particular, Articles L. 225-129-2, L. 225-129-4, L. 225-135, L. 225-138 and L. 228-91 et seq. of the French Commercial Code)<br><br>Maximum nominal amount: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting. | April 5, 2020 (18 months) | The Board of Directors on December 13, 2019, making use of said delegation, approved a cash capital increase for a nominal amount of €214,285.68 through the issue of 5,357,142 new shares with a nominal value of €0.04 without preferential subscription rights to Johnson & Johnson Innovaton - JJDC, Inc, in accordance with this resolution.<br>These shares were issued at €1.40 each, for gross proceeds from the capital increase of €7,499,998.80. |
| October 5, 2018 (17th resolution) | Delegation of authority to be granted to the Board of Directors to issue and allocate share warrants to (i) members and non-voting members of the Board of Directors of the Company in office at the warrant allocation date and who are not employees or executives of the Company or of one of its subsidiaries, (ii) a service provider or consultant under contract to the Company or to one of its subsidiaries, or (iii) members of any committee that the Board of Directors should establish who are not employees or executives of the Company or of one of its subsidiaries.<br>Maximum number of share warrants: 400,000<br>(Articles L. 225-129 et seq. of the French Commercial Code, and in particular, Articles L. 225-129-2, L. 225-129-4, L. 225-135, L. 225-138 and L. 228-91 et seq. of the French Commercial Code) | April 5, 2020 (18 months) | The Board of Directors on November 12, 2018, making use of said delegation, decided to issue 40,000 Warrants (BSAs) to a director of the Company at a price of €0.82, each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €2.76. |

**Summary table of current delegations of authority and powers granted by the Combined General Meeting of July 2, 2020 to the Board of Directors**

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| Combined General Meeting of July 2, 2020 | | | |
| July 2, 2020 (20th resolution) | Delegation of authority granted to the Board of Directors to increase the share capital by issuing ordinary shares and/or any securities giving access to the Company's capital with preferential subscription rights. | September 2, 2022 (26 months) | N/A |

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| | (Articles L. 225-129 to L. 225-129-6, L. 228-91, L. 228-92 and L. 228-93 of the French Commercial Code)<br><br>Maximum nominal amount: €60,000,000, included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | | |
| July 2, 2020 (21st resolution) | Delegation of authority granted to the Board of Directors to increase the share capital by issuing ordinary shares and/or any securities, without preferential subscription rights, through a public offer (excluding an offer targeting a limited number of investors acting on their own behalf or to qualified investors pursuant to L. 411-2-1 of the French Monetary and Financial Code).<br><br>(Articles L. 225-129 to L. 225-129-6, L. 225-135, L. 225-135-1 of the French Commercial Code, and, its Articles L. 225-136, L. 228-91, L. 228-92 and L. 228-93)<br><br>Maximum nominal amount: €60,000,000, included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (22nd resolution) | Delegation of authority granted to the Board of Directors to increase the share capital by issuing ordinary shares and/or any securities, without preferential subscription rights, through an offer targeting a limited number of investors acting on their own behalf or to qualified investors pursuant to L. 411-2-1 of the French Monetary and Financial Code.<br><br>(Articles L. 225-129 et seq., L. 225-195-2, L. 225-135, L. 225-135-1, L. 225-136, L. 228-91, L. 228-92 and L. 228-93 of the French Commercial Code)<br><br>Maximum nominal amount: €60,000,000, included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (24th resolution) | Delegation of authority granted to the Board of Directors to issue ordinary shares giving, where applicable, access to other ordinary shares or to the allocation of debt securities (of the Company or a Group company), and/or securities giving access to future ordinary shares (of the Company or a Group company), without preferential subscription rights for shareholders, for the benefit of categories of persons meeting pre-determined criteria.<br><br>(Articles L. 225-129-2, L. 225-138 and L. 228-92 of the French Commercial Code)<br><br>Maximum nominal amount: 50% of the capital on the date of issue of the securities, | January 2, 2022 (18 months) | The Board of Directors on July 7, 2020 making use of said delegation, decided to issue 500,000 share warrants (BSA EIB Tranche 2) with a nominal value of €0.01 reserved in whole for the European Investment Bank as part of the drawdown of the second tranche of the financing agreement, each giving the right to subscribe to an ordinary share of the Company with a par value of €0.04. The exercise price is equal to the volume weighted average of the last three trading days preceding their issue, less a 5% discount. |

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| | included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | | |
| July 2, 2020 (25th resolution) | Delegation of authority for the Board to increase the number of securities to be issued in the event of a capital increase with or without preferential subscription rights in accordance with the delegations above.<br><br>(Articles L. 225-129, L. 225-129-2, L. 225-135, L. 225-135-1 et seq., L. 228-91 and L. 228-92 of the French Commercial Code)<br><br>The overall nominal amount of any capital increase will be included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (26th resolution) | Delegation of authority granted to the Board of Directors to issue ordinary shares and securities giving access to the Company's capital, in the event of a public offer with an exchange component initiated by the Company.<br><br>(Articles L. 225-129 to L. 225-129-6, L. 225-148, L. 228-91 and L. 228-92 of the French Commercial Code)<br><br>Maximum nominal amount: €60,000,000, included in the overall maximum amount of €60,000,000. | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (27th resolution) | Delegation of authority granted to the Board of Directors to increase the share capital, within a limit of 10% of the share capital, as consideration for contributions in kind of equity securities or securities giving access to the share capital of other companies and not part of a public exchange offering.<br><br>(Article L. 225-147 of the French Commercial Code)<br><br>Maximum nominal amount: €60,000,000, included in the overall maximum amount of €60,000,000. | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (29th resolution) | Delegation of authority granted to the Board of Directors to increase capital through incorporation of premiums, reserves, earnings or other.<br><br>(Articles L. 225-129, L. 225-129-2 and L. 225-130 of the French Commercial Code)<br><br>Maximum nominal amount: €24,000 independent ceiling | September 2, 2022 (26 months) | N/A |
| July 2, 2020 (30th resolution) | Authorization granted to the Board of Directors to grant existing and/or new bonus shares to employees and/or certain corporate officers of the Company or of related companies, waiver by shareholders of their preferential subscription rights, term of the authorization, ceiling, length of vesting | September 2, 2023 (38 months) | N/A |

| Date of the Annual General Meeting | Purpose of the authorization | Expiration date | Use made by the Board of Directors |
|---|---|---|---|
| | periods, in particular in the event of disability and, where applicable, holding periods.<br><br>(Articles L. 225-197-1 and L. 225-197-2 of the French Commercial Code)<br><br>Ceiling: 500,000 shares with a nominal value of €0.04. | | |
| July 2, 2020 (31st resolution) | Authorization granted to the Board of Directors to grant stock options on the Company's shares, in accordance with the provisions of Articles L. 225-177 et seq. of the French Commercial Code, with the waiver by shareholders of their preferential subscription rights.<br><br>(Articles L. 225-177 et seq. of the French Commercial Code)<br><br>Ceiling: 500,000 shares with a nominal value of €0.04. | September 2, 2023 (38 months) | N/A |
| July 2, 2020 (32nd resolution) | Delegation of authority to be granted to the Board of Directors to issue and allocate share warrants without preferential subscription rights to (i) members and non-voting members of the Board of Directors of the Company in office at the warrant allocation date and who are not employees or executives of the Company or of one of its subsidiaries, (ii) a service provider or consultant under contract to the Company or to one of its subsidiaries, or (iii) members of any committee that the Board of Directors established or should establish who are not employees or executives of the Company or of one of its subsidiaries.<br><br>(in particular Articles L. 225-132, L. 225-138-1 and L. 228-91 et seq. of the French Commercial Code)<br><br>Maximum number of share warrants: 400,000 | January 2, 2022 (18 months) | N/A |
| July 2, 2020<br><br>(33rd resolution) | Delegation granted to the Board of Directors to increase the share capital by issuing shares and securities giving access to the Company's share capital without preferential subscription rights for the benefit of employees who are members of a Group savings plan.<br><br>(Articles L. 225-129 et seq. and L. 225-138-1 of the French Commercial Code and L. 3332-1 et seq. of the French Labor Code)<br><br>Maximum nominal amount: €100,000, included in the overall maximum amount of €60,000,000 set by the Annual General Meeting. | September 2, 2022<br><br>(26 months) | N/A |

### 21.1.6 Information on the capital of any member of the Group subject to an option or a conditional or unconditional agreement to be put under option

To the knowledge of the Company, no call or put options or other obligations exist in favor of the Company's shareholders or are approved by the latter with respect to the Company's shares.

### 21.1.7 History of share capital

**Changes in share capital since the creation of the Company**

This table retraces changes in the Company's share capital since its creation. This is historical data, taking into account the 4-for-1 reverse stock split authorized by the General Meeting on May 25, 2011.

The sums raised are detailed in Section 10.1.1of this Universal Registration Document.

| Date | Type of transaction | Number of shares created | Number of shares comprising the capital | Nominal amount (€) | Share capital (€) | Share premium | Issue Price or option price (€) |
|---|---|---|---|---|---|---|---|
| 04/21/2000 | Constitution | 62 000 | 62 000 | 1,00 | 62 000,00 | | 4,00 |
| 07/04/2000 | 100-for-1-share split | 6 138 000 | 6 200 000 | 0,01 | 62 000,00 | | 0,04 |
| 09/21/2000 | Cash issue of O shares | 3 233 100 | 9 433 100 | 0,01 | 94 331,00 | 1 557 707,58 | 1,967 |
| 2003 | Cash issue of O shares | 3 820 400 | 13 253 500 | 0,01 | 132 535,00 | 2 128 344,84 | 2,268 |
| 2004 | Cash issue of O shares | 3 062 234 | 16 315 734 | 0,01 | 163 157,34 | 2 774 384,00 | 3,664 |
| 2006 | Cash issue of O shares | 1 926 978 | 18 242 712 | 0,01 | 182 427,12 | 2 248 397,93 | 4,707 |
| 2007 | Exercise of BSPCE | 20 950 | 18 263 662 | 0,01 | 182 636,62 | 13 747,20 | |
| 2007 | Cash issue of P shares | 8 447 419 | 26 711 081 | 0,01 | 267 110,81 | 11 730 930,77 | 3,664 |
| 2007 | Bond conversions | 1 869 477 | 28 580 558 | 0,01 | 285 805,58 | 2 181 305,76 | 5,595 |
| 2008 | Exercise of BSPCE | 529 500 | 29 110 058 | 0,01 | 291 100,58 | 292 179,60 | |
| 2008 | Cash issue of P shares | 6 082 345 | 35 192 403 | 0,01 | 351 924,03 | 8 446 552,50 | 5,595 |
| 2010 | Exercise of BSPCE | 5 000 | 35 197 403 | 0,01 | 351 974,03 | 4 950,00 | |
| 2010 | Exercise of BSA | 530 376 | 35 727 779 | 0,01 | 357 277,79 | | |
| 05/02/2011 | Exercise of BSPCE | 1 | 35 727 780 | 0,01 | 357 277,80 | 0,99 | |
| 05/25/2011 | 4-for-1 reverse stock split | - 26 795 835 | 8 931 945 | 0,04 | 357 277,80 | | NA |
| 07/11/2011 | Capital increase | 4 346 243 | 13 278 188 | 0,04 | 531 127,52 | 56 327 309,28 | 13,00 |
| 2011 | Exercise of Stock Options | 1 000 | 13 279 188 | 0,04 | 531 167,52 | | |
| 2011 | Exercise of BSPCE | 124 028 | 13 403 216 | 0,04 | 536 128,64 | | |
| 2012 | Exercise of BSA/BSPCE | 151 343 | 13 554 559 | 0,04 | 542 182,36 | 586 536,28 | |
| 2012 | Exercise of Stock Options | 7 187 | 13 561 746 | 0,04 | 542 469,84 | 28 460,52 | |
| 2013 | Exercise of BSPCE | 189 875 | 13 751 621 | 0,04 | 550 064,84 | | |
| 2013 | Exercise of Stock Options | 51 836 | 13 803 457 | 0,04 | 552 138,28 | | |
| 2014 | Exercise of BSPCE | 184 375 | 13 987 832 | 0,04 | 559 513,28 | | |
| 2014 | Exercise of Stock Options | 4 687 | 13 992 519 | 0,04 | 559 700,76 | | |
| 2015 | Exercise of Stock Options | 34 000 | 14 026 519 | 0,04 | 561 060,76 | | |
| 2015 | Exercise of BSA | 70 000 | 14 096 519 | 0,04 | 563 860,76 | | 5,03 |
| 2015 | Exercise of BSA | 70 000 | 14 166 519 | 0,04 | 566 660,76 | | 5,04 |
| 2015 | Exercise of BSA | 70 000 | 14 236 519 | 0,04 | 569 460,76 | | 4,56 |
| 05/12/2015 | Capital increase | 1 189 251 | 15 425 770 | 0,04 | 617 030,80 | | 3,95 |
| 2015 | Exercise of BSPCE | 50 937 | 15 476 707 | 0,04 | 619 068,28 | | |
| 2015 | Exercise of BSA | 100 000 | 15 576 707 | 0,04 | 623 068,28 | | 3,11 |
| 2015 | Exercise of BSA | 100 000 | 15 676 707 | 0,04 | 627 068,28 | | 3,15 |
| 2015 | Exercise of BSA | 100 000 | 15 776 707 | 0,04 | 631 068,28 | | 3,15 |
| 2015 | Exercise of BSA | 250 000 | 16 026 707 | 0,04 | 641 068,28 | | 3,08 |
| 2015 | Exercise of BSA | 150 000 | 16 176 707 | 0,04 | 647 068,28 | | 3,08 |
| 07/12/2016 | Capital increase | 2 980 131 | 19 156 838 | 0,04 | 766 273,52 | 3 887 702,80 | 1,49 |
| 2016 | Exercise of BSA | 250 000 | 19 406 838 | 0,04 | 776 273,52 | | 3,15 |
| 2016 | Exercise of BSA | 50 000 | 19 456 838 | 0,04 | 778 273,52 | | 3,03 |
| 2016 | Exercise of BSA | 75 000 | 19 531 838 | 0,04 | 781 273,52 | | 2,95 |
| 2016 | Exercise of BSA | 120 000 | 19 651 838 | 0,04 | 786 073,52 | | 3,03 |
| 2016 | Exercise of BSA | 100 000 | 19 751 838 | 0,04 | 790 073,52 | | 2,9 |
| 2016 | Exercise of BSA | 100 000 | 19 851 838 | 0,04 | 794 073,52 | | 2,9 |
| 2016 | Exercise of BSA | 50 000 | 19 901 838 | 0,04 | 796 073,52 | | 2,83 |
| 2016 | Exercise of BSA | 50 000 | 19 951 838 | 0,04 | 798 073,52 | | 2,75 |
| 2016 | Exercise of BSA | 50 000 | 20 001 838 | 0,04 | 800 073,52 | | 2,9 |
| 2017 | Exercise of BSA - Kepler - Plan of the 11/18/2016 | 1 005 000 | 21 006 838 | 0,04 | 840 273,52 | 2 700 267,00 | |
| 2017 | Exercise of BSA - Kepler - Plan of the 10/06/2017 | 2 100 000 | 23 106 838 | 0,04 | 924 273,52 | 7 627 047,50 | Moyenne de 3,74 |
| 2017 | Exercise of BSA - Kepler - Plan of the 12/01/2017 | 1 200 000 | 24 306 838 | 0,04 | 972 273,52 | 4 868 244,00 | Moyenne de 4,18 |
| 2017 | Exercise of BSPCE | 24 000 | 24 330 838 | 0,04 | 973 233,52 | 95 080,00 | 5,06 |
| 2017 | Exercise of SO | 16 500 | 24 347 338 | 0,04 | 973 893,52 | 31 850,00 | 4,4 |
| 2018 | Exercise of BSA - Kepler - Plan of the 12/01/2017 | 850 000 | 25 197 338 | 0,04 | 1 007 893,52 | 3 745 937,50 | Moyenne de 4,51 |
| 2018 | Exercise of SO | 4 000 | 25 201 338 | 0,04 | 1 008 053,52 | 10 000,00 | 2,54 |
| 2019 | Reserved capital increase | 5 357 142 | 30 558 480 | 0,04 | 1 222 339,20 | 7 825 713,00 | 1,4 |
| 2019 | Preferred shares | 13 260 | 30 571 740 | 0,04 | 1 222 869,60 | | 0,04 |

## 21.2 Memorandum and bylaws

### 21.2.1 Corporate purpose

The Company aims to do the following in France and abroad:

- Design, develop and market scientific instruments, in particular optical medical imaging instruments, using all existing or future technological resources;
- All research activities in order to develop, register and use all process patents and industrial or intellectual property rights as well as all transactions relating to these patents and these rights;
- All of which directly or indirectly on its behalf or on behalf of third parties, whether alone or with third parties, through the creation of new companies, partnership contributions, mergers, partnerships, joint ventures or transfers instead of payments by means of renting or leasing any assets, claims or otherwise;
- And generally, any financial, commercial, industrial, moveable, real estate and financial transactions, that might relate directly or indirectly to any of the stated purposes or any other similar purpose designed to develop the Company's assets.

### 21.2.2 Provisions of the bylaws or other provisions concerning the members of the administrative and governing bodies

**Board of Directors**

(a) Composition of the Board of Directors (Articles 11.1 and 11.2 of the bylaws)

The Company is managed by a Board consisting of natural and legal persons whose number is set by the Ordinary General Meeting within the limits set out by law.

Any legal person must, upon its appointment, designate a natural person as a permanent representative on the Board of Directors. The permanent representative's term of office shall be the same as that of the legal person director he or she represents. When the legal person dismisses its permanent representative, it must immediately find a replacement. The same provisions shall apply in case of the permanent representative's death or resignation.

The term of office of the Directors shall be two years. The term of office of a Director shall end after the Ordinary Annual General Meeting deciding on the past financial year's accounts held in the year in which the term of office of said Director expires.

The Directors may always be reelected; they may be dismissed at any time by a decision of the Annual General Meeting.

If one or more Board of Directors' seats become vacant because of death or resignation, the Board of Directors may, between two General Meetings, make appointments ad interim.

The appointments made by the Board, in line with the paragraph above, shall be subject to ratification by the next Ordinary Annual General Meeting.

If there is no ratification, the decisions made and the procedural measures carried out earlier by the Board shall remain in effect.

When the number of Directors falls below the legal minimum, the remaining Directors must immediately convene an Ordinary General Meeting in order to complete the Board's membership.

A Company employee may be appointed as a Director. His or her employment contract must, however, correspond to actual employment. Said employee will not, in that case, lose the benefit of his or her employment contract.

The number of Directors who are linked to the Company through an employment contract may not exceed one-third of the Directors in office.

The number of Directors who are more than 70 years of age may not be greater than one-third of the Directors in office. When this limit is exceeded during a term of office, the oldest Director shall automatically be deemed to have resigned following the next Annual General Meeting.

The Board of Directors shall elect from among its members a Chairman who must be a natural person. It shall determine the term of the Chairman's duties, which may not be greater than his or her term of office as a Director, and the Board may dismiss the Chairman at any time. The Board will set his or her compensation.

The Chairman organizes and conducts the activities of the Board, and reports these to the General Meeting. The Chairman shall monitor the efficient working of the Company's bodies and shall ensure, in particular, that the Directors are able to carry out their duties.

The Chairman of the Board may not be older than 75 years of age. If the Chairman reaches that age limit during his or her term of office as Chairman, he or she shall be deemed to have resigned. The Chairman's term of office shall continue, however, until the next meeting of the Board of Directors during which the Chairman's successor will be appointed. Subject to this provision, the Chairman of the Board may always be reelected.

(b) Non-voting Board members (Article 15 of the bylaws)

The Ordinary General Meeting may, at the recommendation of the Board of Directors, appoint non-voting Board members. The Board of Directors may also appoint non-voting Board members directly, subject to ratification by the next General Meeting.

The non-voting Board members, whose number may not be greater than five, shall constitute a panel. They are selected freely on the basis of their qualifications.

They are appointed for a three-year term that ends following the Ordinary Annual General Meeting that has ruled on the accounts of the past financial year.

The panel of non-voting Board members shall examine the questions that the Board of Directors or its Chairman submits, for opinion, to its review. The non-voting Board members shall attend the Board of Directors' meetings and shall participate in the deliberations in an advisory capacity only, without their absence affecting the validity of the deliberations.

They are convened to the Board's meetings under the same conditions as the Directors.

The Board of Directors may pay the non-voting Board members by deducting an amount from the attendance fees allocated by the General Meeting to the Directors.

(c) Meeting of the Board of Directors (Article 12 of the bylaws)

The Board of Directors shall meet as often as the Company's interest requires.

The Directors shall be convened by the Chairman to attend the Board's meetings. Meeting notices may be given in writing or orally.

The CEO may also ask the Chairman to convene the Board of Directors on a specific agenda.

Moreover, the Directors representing at least one-third of the Board members may validly convene the Board. In this case, they must specify the agenda of the meeting.

When a Works Council is established, this Council's representatives, appointed in accordance with the provisions of the French Labor Code, must be convened to all Board of Directors' meetings.

The Board meetings shall take place either at the registered office or any other venue in France or outside France.

In order for the Board's decisions to be valid, the number of members present must at least be equal to half of the members.

The decisions of the Board of Directors shall be taken by a majority vote; in case of a tie, the Chairman at the meeting will have the casting vote.

The internal rules that the Board of Directors may adopt, could provide in particular that the Directors who take part in the Board's meeting through videoconferencing or other telecommunications means in compliance with applicable regulations shall be deemed present for calculation of the quorum and majority. This provision shall not apply for the adoption of the decisions referred to in Articles L. 232-1 and L. 233-16 of the French Commercial Code.

Each Director shall receive the information necessary to fulfill his or her mandate and term of office, and may obtain all documents that he or she deems useful.

Every Director may give power of attorney, including by letter, telegram, telex, fax, email or any other means of electronic communication, to another Director in order to represent him or her at a Board meeting. However, no Director may have more than one power of attorney at any one meeting.

Copies of, or excerpts from, the Board of Directors' decisions shall be validly certified by the Chairman of the Board of Directors, the Chief Executive Officer, the Director who is temporarily assigned the duties of Chairman, or an agent empowered for that purpose.

(d) Powers of the Board of Directors (Article 13 of the bylaws)

The Board of Directors shall determine the general direction of the Company's business and shall ensure its implementation. Subject to the powers expressly granted to the General Meetings, and within the limit of the Company purpose, the Board will deal with any question pertaining to the smooth running of the Company and will settle the business that concerns the Company in its deliberations.

In its relations with third parties, the Company is bound even by the actions of the Board of Directors that do not fall under the Company purpose, unless it establishes that the third party knew that the action was beyond said purpose or that it could not fail to know under the circumstances, it being excluded that the publication of the bylaws alone is sufficient to constitute this evidence.

The Board of Directors shall carry out the verifications and inspections that it deems advisable.

Moreover, the Board of Directors shall have the special powers conferred to it by law.

**General Management**

The Company's General Management will be handled, under his or her responsibility, either by the Chairman of the Board or by another individual appointed by the Board of Directors holding the title of Chief Executive Officer (CEO).

The CEO shall be vested with the most extensive powers to act in all circumstances on behalf of the Company. He or she shall exercise his or her powers within the limit of the Company purpose and subject to the powers that the law expressly confers on General Meetings and the Board of Directors.

He or she shall represent the Company in its relations with third parties. The Company shall be bound even by the actions of the CEO that do not fall under the Company purpose, unless it proves that the third party knew that the action was beyond said purpose or that it could not fail to know under the circumstances, it being excluded that the publication of the bylaws alone is sufficient to constitute this evidence.

The CEO may not be older than 65 years of age. If the CEO reaches this age limit, he or she will be deemed to have resigned. The CEO's term of office will however continue until the next meeting of the Board of Directors during which the new CEO would be appointed.

When the CEO exercises the duties of a Director, the duration of his or her term of office may not exceed his or her term of office as Director.

The Board of Directors may dismiss him at any time. If the dismissal is decided without due cause, it may lead to damages, except when the CEO assumes the functions of Chairman of the Board of Directors.

Following a resolution taken by a majority vote of the Directors present or represented, the Board of Directors shall choose between the two modes for assuming General Management referred to in the first item of paragraph.

Shareholders and third parties shall be informed of that choice under the legal and regulatory conditions.

The choice thus made by the Board of Directors shall remain in effect until the Board decides otherwise or, at the discretion of the Board, for the duration of the CEO's term of office.

When the Company's General Management is assumed by the Chairman of the Board of Directors, the provisions that apply to the CEO shall apply to it.

In accordance with the provisions of Article 706-43 of the French Code of Criminal Procedure, the CEO may validly delegate authority to any person of his or her choice to represent the Company in regard to any prosecution that might be instituted against it.

Upon the recommendation of the CEO, the Board of Directors may instruct one or more individuals to assist the CEO as Deputy CEO.

By agreement with the CEO, the Board of Directors shall determine the scope and term of the powers conferred on the Deputy CEOs. The Board of Directors shall establish their remuneration. When a Deputy CEO holds the title of Director, his or her term of office may not exceed his or her term of office as Director.

With regard to third parties, the Deputy CEOs shall have the same powers as the CEO; the Deputy CEOs shall have, in particular, powers to take part in court proceedings.

The number of Deputy CEOs may not exceed five.

The Deputy CEO(s) may be dismissed at any time by the Board of Directors upon the recommendation of the CEO. If the dismissal is resolved without due cause, it may lead to damages.

A Deputy CEO may not be older than 65 years of age. If a Deputy CEO reaches that age limit during his or her term of office, he or she shall be deemed to have resigned. The Deputy CEO's term of office shall continue, however, until the next meeting of the Board of Directors during which a new Deputy CEO could possibly be appointed.

When the CEO ceases to exercise his or her duties or is prevented from doing so, the Deputy CEO(s) shall keep their duties and responsibilities until the appointment of the new CEO unless otherwise decided by the Board of Directors.

### 21.2.3 Rights, privileges and restrictions attached to the Company's shares

**Type of securities (Article 7 of the bylaws)**

Fully paid-up shares are in registered or bearer form, as the shareholder so chooses, subject, however, to the application of legal provisions relating to the form of shares held by certain individuals or legal persons. Shares that have not been fully paid up must be in registered form.

Shares are registered in an account subject to the conditions and according to the procedures laid down by the applicable legal and regulatory provisions.

Ownership of shares issued in registered form is evidenced by their entry in the registered share account.

**Voting rights (Article 9 of the bylaws)**

The rights and obligations attached to a share are transferred therewith, and the transfer includes all dividends accruing, due and not paid and, where applicable, the share of any reserves and provisions.

Share ownership automatically implies approval by the shareholder of these bylaws and of the resolutions of Annual General Meetings of the shareholders.

Unless otherwise provided by law, in the case of double voting rights or in the case of preferred shares, each shareholder has as many voting rights and may cast as many votes at General Meetings as the paid-up shares held. For the same par value, and without prejudice to the double voting right provided for below, each capital or dividend share carries the right to one vote.

A double voting right to that carried by other shares, in view of the percentage of the share capital they represent, is assigned to all fully paid-up shares (of any category) which can be shown to have been registered for at least three years in the name of the same shareholder. It is stipulated that the conversion of preferred shares into ordinary shares will not affect the calculation of the holding period. This right is also conferred, from issue, in the event of a capital increase by incorporation of reserves, profits or share premiums on bonus registered shares awarded to shareholders based on their existing shares by virtue of which they already enjoy such a right.

Preferred shares do not carry any right to vote at Annual General Meetings. However, beneficiaries of preferred shares will be called to a special meeting under the conditions stipulated by Article L. 225-99 of the French Commercial Code to approve any modification to the rights attached to preferred shares.

Shareholders may, by registered letter with requested return receipt sent to the Company, waive their double voting rights temporarily or permanently and in whole or in part. Said waiver shall take effect on the third business day after the Company receives the waiver notice.

Whenever several securities or shares, whether preferred or otherwise, need to be held in order to exercise a particular right, the shareholders or securities holders shall be responsible for acquiring the necessary number of shares or securities.

**Rights to dividends and profits (Articles 9, 21 and 22 of the bylaws)**

Each share shall carry the right, in the ownership of the Company's assets and in the distribution of profits and the liquidation surplus, to a share proportional to the number and par value of the existing shares, with the exception of preferred shares which do not benefit from any dividend and do not give any entitlement to reserves but entitle holders to the same rights to the liquidation surplus as ordinary shares.

A deduction of at least five percent (5%) must be made from the profit of the financial year, minus previous losses, if any, which deduction will be allocated for the establishment of a reserve fund called "legal reserve". Said deduction will no longer be mandatory once the amount of legal reserve reaches one-tenth of the share capital.

The distributable profit shall comprise the profit of the financial year minus the previous losses and the deduction set forth in the paragraph above, plus the profit carried forward.

If the financial year's accounts, as approved by the General Meeting, result in distributable profit, the General Meeting will decide to record it under one or more reserve items for which it will decide the allocation or use, to carry it forward or to distribute it as dividends.

After recognizing the existence of reserves that are available, the General Meeting may resolve to distribute amounts deducted from these reserves. In that case, the resolution shall specify expressly the reserve items from which these deductions are made. However, the dividends are first deducted from the distributable profit of the financial year.

The terms for paying the dividends shall be established by the General Meeting or, otherwise, by the Board of Directors.

However, the dividend payment must be made no later than nine months after the end of the financial year.

The General Meeting ruling on the accounts of the financial year may give each shareholder, for all or part of the dividend distributed, a choice between paying the dividend in cash or in shares.

Likewise, the Ordinary General Meeting, ruling under the conditions provided for by Article L. 232-12 of the French Commercial Code, may in the event of payment to each shareholder of an interim dividend authorized by the Board of Directors, and for all or some of said interim dividend, allow the Board of Directors to offer a choice between payment of the interim dividend in cash or in shares.

The offer of payment in shares, the price and the conditions of issue of the shares, as well as the share payment request and the conditions of performance of the capital increase are governed by applicable law and regulations.

When financial statements prepared during or at the end of the financial year and certified by the statutory auditors indicate that the Company, since the previous year-end, after amortization, depreciation and provisions and less any prior losses, in addition to amounts to be allocated to reserves in pursuance of the law or these bylaws and taking into account retained earnings, has made a profit, the Board of Directors may decide to distribute an interim dividend before approval of the financial statements for the period and set the amount and date of distribution. The amount of such interim dividends may not exceed the amount of profit defined in this paragraph. Otherwise, the Board of Directors may not exercise the option described above.

**Preferred subscription right**

The Company's shares give the right to a preferred subscription right with regard to increases in share capital under the conditions set forth by the French Commercial Code, with the exception of preferred shares which do not benefit from preferred subscription rights, it being specified, however, that the conversion ratio will be adjusted in order to preserve the rights of their beneficiaries.

**Limitation of voting rights**

No clause in the bylaws restricts the voting right attached to the shares.

**Identifiable bearer securities**

Subject to applicable legal and regulatory conditions, the Company may also request at any time, at its own expense, from any qualified organization, the name, or, if it is a legal person, the company name, nationality and address of the holders of securities conferring immediate or future voting rights in its own General Meetings, as well as the number of securities held by each and, as the case may be, the restrictions that may apply to these securities.

Company buyback of its own shares

See Section 21.1.3of this Universal Registration Document.

### 21.2.4 Amendment terms and conditions of shareholders' rights

The shareholders' rights, as set out in the Company's bylaws, may only be amended by the Company's Extraordinary Annual General Meeting.

### 21.2.5 General Meetings of Shareholders

(a) Holding of General Meetings (Article 19 of the bylaws)

General Meetings are convened and held under the conditions set forth by law.

When the Company wishes to convene the meeting through electronic communication instead of postal mail, it must first receive the approval of the shareholders concerned who will specify their electronic mail addresses.

Meetings shall be held at the registered office or any other venue specified in the meeting notice.

The right to participate in the meetings shall be governed by applicable legal and regulatory provisions, and shall in particular be conditional on the accounting registration of the securities under the name of the shareholder or the proxy registered on the shareholder's behalf three business days prior to the meeting at 12:00 a.m., Paris time, either in the accounts of registered securities held by the Company, or in the accounts of bearer securities held by the authorized proxy.

If the shareholder is unable to attend the meeting in person, he or she may select one of the following three options:

- grant a power of attorney under the conditions authorized by law and regulations;
- vote by absentee ballot; or
- send a power of attorney to the Company, without indicating a proxy,

under conditions pursuant to the law and regulations.

The Board of Directors may organize, under the conditions provided for by applicable laws and regulations, the shareholders' participation and vote at meetings through videoconferencing or other telecommunications enabling them to be identified. If the Board of Directors decides to avail itself of this option for a specific meeting, this decision will be stated in the meeting notice. Shareholders taking part in meetings through videoconferencing or any of the other aforesaid telecommunications means, according to what the Board of Directors chooses, shall be deemed present for calculation of the quorum and majority.

Meetings shall be chaired by the Chairman of the Board of Directors or, if absent, by the CEO, a Deputy CEO if the latter is a Director or a Director specifically appointed for this purpose by the Board. Otherwise, the meeting will elect its Chairman.

The duties of tellers shall be carried out by the two members attending the meeting who, accepting these duties, have the greatest number of votes. The bureau of the General Meeting shall appoint the secretary, who need not be a shareholder.

An attendance sheet will be kept under the conditions laid down by law.

The Ordinary Annual General Meeting convened pursuant to the first meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fifth of the shares with voting rights. The Ordinary Annual General Meeting convened pursuant to a second meeting notice shall constitute a quorum irrespective of the number of present or represented shareholders.

The decisions of the Ordinary Annual General Meeting shall be taken by a majority vote by the present or represented shareholders. The votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or whose vote was blank or void.

The Extraordinary Annual General Meeting convened pursuant to the first meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fourth of the shares with voting rights. The Extraordinary Annual General Meeting convened pursuant to a second meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fifth of the shares with voting rights.

The decisions of the Extraordinary Annual General Meeting shall be taken by a two-thirds majority of the shareholders present or represented. The votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or whose vote was blank or void.

Copies or extracts of the meeting's minutes shall be validly certified by the Chairman of the Board of Directors, a Director acting as CEO, or by the meeting secretary.

(b) Powers of meetings (Article 19 of the bylaws)

Ordinary and Extraordinary General Meetings of the Shareholders shall exercise their respective powers under the conditions laid down by law.

### 21.2.6 Provisions that delay, postpone or prevent a change in control

The Company's bylaws do not contain any provisions that enable delaying, postponing or preventing a change in control.

#### 21.2.7 Exceeding the statutory thresholds (Article 8.3 of the bylaws)

Any natural or legal person, acting alone or in concert with others, who holds, in any manner whatsoever, as defined by Articles L. 233-7 et seq. of the French Commercial Code, directly or indirectly, a share equal to three percent (3%) of the Company's share capital or voting rights, must disclose to the Company the information referred to in Article L. 233-7-I of the French Commercial Code (in particular the total number of shares and voting rights said person holds), by registered letter with return receipt requested, or by any equivalent means for persons residing outside France, sent to the registered office within four trading days of the date on which the threshold is crossed.

This obligation also applies, under the conditions above, each time a new 3% threshold of the Company's share capital or voting rights is reached or exceeded, whatever the reason therefore may be, including above the 5% legal threshold.

Any shareholder whose stake in the share capital or voting rights falls below one of the thresholds set forth above must also inform the Company thereof within the same period of four trading days and according to the same terms.

In the event of non-compliance with this provision and upon request by one or more shareholders holding at least five percent of the Company's share capital or voting rights, the shares that exceed the portion that should have been notified shall be deprived of voting rights at any General Meeting to be held until expiry of a two-year period following the date when the notification was cured.

#### 21.2.8 Specific provisions governing changes to the share capital

The Company's bylaws do not have any special provision governing changes to its share capital.

## 21.3 Insurance and risk coverage

The Company has purchased a policy that covers the principal insurable risks and has the coverage amounts it deems compatible with the nature of its business. The policies the Group benefits from today are the following:

| Insurance policy/risks covered | Insurer | Amount of guarantees |
|---|---|---|
| **Comprehensive corporate insurance** | AXA | |
| Fire and secondary risks | | Ceiling €8.8 million |
| Broken glass | | €15,000 |
| Operating losses | | €8,016,000 |
| **Broken machinery** | AXA | |
| Cellvizio loaned or leased to a healthcare facility | | €350,000 |
| Investment guarantee | | €100,000 Equipment exhibited at a show (one per month) |
| **Civil operating liability** | CHUBB | Per year €8,500,000 |
| All bodily injury, property damage and non-material damages taken together without the ability to exceed for the following damages: | | |
| - Inexcusable fault/occupational illness | | €2,000,000 |
| - Property and non-material damage | | €4,000,000 |
| - Non-consequential and non-material damage | | €300,000 |
| - Damage resulting from accidental damage to the environment (off-site subject to authorization) | | €750,000 |
| **Criminal defense - Appeal** | | €30,000 |
| **Civil liability/products** | | |
| All damage taken together resulting from Civil Liability Products: | | €4,000,000 ($5,000,000 for the United States) |
| - Of which non-consecutive non-material damages (coverage not acquired in the United States and Canada) | | €500,000 |
| - Including recall expenses incurred by third parties or the Insured outside of the USA and/or Canada | | €500,000 |
| - Including recall expenses incurred by third parties or the Insured in the USA and/or Canada | | €500,000 |

| | | |
|---|---|---|
| **Assistance to persons travelling** | AXA | |
| All travelers (Company and Subsidiary) | | |
| Personal accident insurance | | €50,000 |
| Civil liability insurance | | €4,500,000 |
| **Key persons accident** | CHUBB | €150,000/person<br>€450,000/event |
| Risks covered:<br>-Accidental death<br>-Total irreversible loss of autonomy | | |
| 3 persons concerned: Chief Executive Officer, VP Finance and Scientific Director | | |
| Employer's liability | | |
| **Employer's liability** | Chartis Insurance | €500,000 per year |
| Civil liability following a breach of employment law<br>Defense<br>Legal advice | | |
| **Liability of corporate officers** | AIG | €5,000,000 |
| All de jure and de facto senior managers (Company and Subsidiary) | | |
| Transported merchandise | AGCS | Sales price<br>Max: €1.5 M / claim |

# SECTION 22
# 22. MATERIAL CONTRACTS

With the exception of the licenses and research and development agreements described in Section 11of this Universal Registration Document, as well as the contracts described below, the Group has not entered into any significant agreements other than those entered into in the normal course of its business.

As an extension of the original contract signed in 2010, the Company in early 2015 and again in early 2019 renewed its supply contract for optical fibers and assemblies with Fujikura, a Japanese corporation which is the Company's sole supplier of optical fibers.

The signing of this type of agreement between Fujikura and the Company ensures that the manufacture and marketing of its products are compliant with ISO 13485 and ISO 9001 standards, and that the products are compliant with the Company's technical specifications and other quality references provided for in the agreement. It also sets out the terms of the relationship with this key supplier. The Company is confident in its ability to renegotiate its contracts with Fujikura on terms that should not adversely impact its business.

Since August 2018, the Company has chosen to work with a preferred partner in China, the company Shanghai YouHe Medical Technology Co., Ltd. based in Shanghai. It will sell Cellvizio for gastroenterological and pulmonary applications in China and will integrate the Cellvizio platform into its commercial offers for advanced endoscopy systems for the aforementioned segments. The marketing territory allocated to Shanghai YouHe Medical Technology Co., Ltd. includes southern and eastern China. The Company is continuing its search to identify a marketing partner for the northern regions of China.

On December 16, 2019, the Company announced a capital increase for the benefit of Johnson & Johnson Innovation - JJDC, Inc. for an amount of €7.5 million, described in a press release of the same date. For a period of 12 months from the settlement date of the new ordinary shares, Johnson & Johnson Innovation - JJDC, Inc. has undertaken to the Company (i) to hold the shares it owns and (ii) not to acquire any new shares that would bring its holding threshold to more than 19.9% of the Company's share capital and voting rights. JJDC will have no right of representation on the Company's Board of Directors.

In addition, the Company has granted, for a period of 24 months, Johnson & Johnson Innovation - JJDC, Inc. and its affiliates a right of first refusal in the event of an agreement (other than a change of control of the Company) for its pCLE (CLE probe) or nCLE (CLE needle) products for endoluminal robotic procedures for pulmonary applications and machine learning and artificial intelligence applications for pulmonary applications. The Company also granted Johnson & Johnson Innovation - JJDC, Inc. and its affiliates, for a period of 24 months, a right of first negotiation in the event of an agreement (other than a change of control of the Company) regarding its pCLE (CLE probe) or nCLE (CLE needle) products for robotic endoluminal procedures for gastrointestinal or urological applications.

**SECTION 23**

# 23. PUBLICLY AVAILABLE DOCUMENTS

Copies of this Universal Registration Document are available free of charge at the Company's head office, 9 rue d'Enghien, 75010 Paris, France. This Universal Registration Document may also be viewed on the Company's website (www.maunakeatech.com) and on the AMF website (www.amf-france.org).

The bylaws, minutes from General Meetings and other corporate documents of the Company, as well as the historical financial information and any evaluation or representation drawn up by an expert at the Company's request that must be made available to the shareholders, in accordance with applicable legislation, may be consulted, free of charge, at the registered office of the Company.

Regulated information within the meaning of the AMF General Regulation is also available on the Company's website (www.maunakeatech.com).

# SECTION 24
# 24. DISCLOSURES ON EQUITY INVESTMENTS

The information concerning the subsidiary Mauna Kea Technologies Inc. is included 7Sections 88 of this Universal Registration Document.

# SECTION 25
# 25. CORRESPONDENCE TABLE

## 25.1 Correspondence table - Rubrics of Appendices 1 and 2 of the Delegated European Regulation No. 2019/980

To make it easier to read this Universal Registration Document, the correspondence table presented below enables the main information required to be identified by Appendices 1 and 2 of the Delegated European Regulation No.2019/980 of March 14, 2019.

| New URD references | Appendices 1 and 2 of the Delegated European (EC) Regulation No. 2019/980 of March 14, 2019 | URD 2019 section |
|---|---|---|
| Section 1 | PERSONS RESPONSIBLE, THIRD-PARTY INFORMATION, EXPERT REPORTS AND APPROVAL OF THE COMPETENT AUTHORITY | |
| 1.1 | Persons responsible for the information | 1.1<br>1.3 |
| 1.2 | Attestation of the persons responsible for the document | 1.2 |
| 1.3 | Expert statement | 1.4 |
| 1.4 | Other statements in the case of third-party information | 1.5 |
| 1.5 | Statement relating to the approval of the document | AMF insert-Cover page |
| Section 2 | STATUTORY AUDITORS | |
| 2.1 | Contact details | 1.1 |
| 2.2 | Changes | 2.1 |
| Section 3 | RISK FACTORS | |
| 3.1 | Description of significant risks | 4 |
| Section 4 | INFORMATION ABOUT THE ISSUER | |
| 4.1 | Company name and business name | 5.1.1 |
| 4.2 | RCS registration and LEI identifier | 5.1.2 |
| 4.3 | Date and term of incorporation | 5.1.3 |
| 4.4 | Head office - legal form - applicable legislation - website - others | 5.1.4 |
| Section 5 | OVERVIEW OF ACTIVITIES | |
| 5.1 | Main activities | 6.1 |
| 5.1.1 | Nature of operations and main activities | 6.1 |
| 5.1.2 | New products and/or services | 6.2 |
| 5.2 | Main markets | 6.4 |
| 5.3 | Significant events | 6.1 |
| 5.4 | Strategy and financial and non-financial objectives | 6.4.1<br>6.5.1<br>6.5.3 |
| 5.5 | Degree of dependence | |
| 5.6 | Competitive position | 6.4.4 |
| 5.7 | Investments | 5.2<br>10.2.2 |
| 5.7.1 | Significant investments made | 5.2<br>10.2.2 |
| 5.7.2 | Significant investments in progress or firm commitments | 5.2<br>10.2.2 |
| 5.7.3 | Joint ventures and significant equity investments | 24 |
| 5.7.4 | Environmental impact from the use of property, plant and equipment | 8.4 |
| Section 6 | ORGANIZATIONAL STRUCTURE | |
| 6.1 | Summary description of the group / Organizational chart | 7.1<br>7.2 |
| 6.2 | List of significant subsidiaries | 7.2 |
| Section 7 | REVIEW OF THE FINANCIAL POSITION AND RESULTS | |
| 7.1 | Financial position | 9.3 |
| 7.1.1 | Discussion of the development and results of activities | 9.2 |
| 7.1.2 | Future development and activities regarding research and development | 6.2 |
| 7.2 | Operating results | 9.2 |
| 7.2.1 | Significant factors | 20.1<br>20.2Appendix, 1.2 |
| 7.2.2 | Significant changes in net sales or net income | 9.2 |

| New URD references | Appendices 1 and 2 of the Delegated European (EC) Regulation No. 2019/980 of March 14, 2019 | URD 2019 section |
|---|---|---|
| Section 8 | CASH AND CAPITAL | |
| 8.1 | Capital of the issuer | 20.110) |
| 8.2 | Cash flows variation | 10.2 |
| 8.3 | Financing needs and structure | 10.3<br>20.111) |
| 8.4 | Restriction on the use of capital | N/A |
| 8.5 | Expected sources of financing | N/A |
| Section 9 | REGULATORY ENVIRONMENT | |
| 9.1 | Description of the regulatory environment and influential exterior factors | 4<br>8.3.2 |
| Section 10 | INFORMATION ON TRENDS | |
| 10.1 | Main recent trends | 12.1 |
| | Significant change in the Group's financial performance since the end of the reporting period | 12.1 |
| 10.2 | Information likely to materially influence the outlook | 12.2 |
| Section 11 | PROFIT PROJECTIONS OR ESTIMATES | |
| 11.1 | Profit projection or estimate in progress | 13 |
| 11.2 | Main assumptions | 13 |
| 11.3 | Certification on the profit projection or estimate | 13 |
| Section 12 | ADMINISTRATIVE, EXECUTIVE AND SUPERVISORY BODIES AND GENERAL MANAGEMENT | |
| 12.1 | Information on the members of administrative bodies and Company general management | 14.1 |
| 12.2 | Conflicts of interest | 14.2 |
| Section 13 | COMPENSATION AND BENEFITS | |
| 13.1 | Compensation and benefits paid or granted | 15.1<br>15.3 |
| 13.2 | Provisions for retirement or others | 15.2 |
| Section 14 | FUNCTIONS OF ADMINISTRATIVE AND EXECUTIVE BODIES | |
| 14.1 | Terms of office | 14.1.1<br>14.1.2 |
| 14.2 | Service contracts | N/A |
| 14.3 | Committees | 16.2 |
| 14.4 | Compliance with the corporate governance rules | 16.3 |
| 14.5 | Potential significant impacts and future governance changes | 14.1 |
| Section 15 | EMPLOYEES | |
| 15.1 | Breakdown of employees | 17.1 |
| 15.2 | Employee shareholding and stock options | 17.2 |
| 15.3 | Employee shareholding agreement | 17.3<br>17.4 |
| Section 16 | PRINCIPAL SHAREHOLDERS | |
| 16.1 | Breakdown of capital | 18.1 |
| 16.2 | Different voting rights | 18.3<br>21.2.3 |
| 16.3 | Control of the issuer | 18.5 |
| 16.4 | Shareholder agreement | 18.6 |
| Section 17 | TRANSACTIONS WITH RELATED PARTIES | |
| 17.1 | Detail of transactions | 19 |
| Section 18 | FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES | |
| 18.1 | Historical financial information | |
| 18.1.1 | Audited historical financial information | 3 |
| 18.1.2 | Change of accounting reference date | |
| 18.1.3 | Accounting standards | 20.11)<br>20.2Appendix, 3 |
| 18.1.4 | Change of accounting framework | |
| 18.1.5 | Minimal content of audited financial information | |
| 18.1.6 | Consolidated financial statements | 20.1 |
| 18.1.7 | Date of most recent financial information | 20.6 |
| 18.2 | Interim financial information and other | N/A |
| 18.2.1 | Quarterly or half-yearly financial information | |
| 18.3 | Audit of historical annual financial information | 20.5 |
| 18.3.1 | Audit report | 20.5 |
| 18.3.2 | Other audited information | |

| New URD references | Appendices 1 and 2 of the Delegated European (EC) Regulation No. 2019/980 of March 14, 2019 | URD 2019 section |
|---|---|---|
| 18.3.3 | Non-audited financial information | |
| 18.4 | Pro forma financial information | N/A |
| 18.4.1 | Significant change in gross values | |
| 18.5 | Dividend policy | 20.8 |
| 18.5.1 | Title | 20.8 |
| 18.5.2 | Amount of dividend per share | 20.1 |
| 18.6 | Legal and arbitration proceedings | 20.9 |
| 18.6.1 | Significant procedures | 20.9 |
| 18.7 | Significant change in the issuer's financial position | 20.10 |
| 18.7.1 | Significant change since the end of the reporting period | 20.10 |
| Section 19 | ADDITIONAL INFORMATION | |
| 19.1 | Share capital | 21.1 |
| 19.1.1 | Amount of issued capital | 21.1.1 |
| 19.1.2 | Shares not representative of capital | 21.1.2 |
| 19.1.3 | Treasury shares | 21.1.3 |
| 19.1.4 | Securities | 21.1.4 |
| 19.1.5 | Conditions of acquisition right and/or any obligation | |
| 19.1.6 | Option or agreement | 21.1.6 |
| 19.1.7 | History of share capital | 21.1.7 |
| 19.2 | Memorandum and bylaws | 21.2 |
| 19.2.1 | Registration in the registrar and company name | 5.1.2<br>21.2.1 |
| 19.2.2 | Categories of existing shares | 21.1.4 |
| 19.2.3 | Provision impacting a change of control | 21.2.6 |
| Section 20 | MATERIAL CONTRACTS | |
| 20.1 | Summary of each contract | 22 |
| Section 21 | AVAILABLE DOCUMENTS | |
| 21.1 | Statement on consultable documents | 23 |

## 25.2 Correspondence table of the annual financial report and the management report pursuant to the French Commercial Code

To make it easier to read the annual financial report and the management report required under the French Commercial Code, the following thematic table shows where to find the main information provided in this Universal Registration Document.

| Rubrics | | Information for | URD 2019 section |
|---|---|---|---|
| **I. COMPANY FINANCIAL STATEMENTS** | | Annual Financial Report | 20.2 |
| **II. CONSOLIDATED FINANCIAL STATEMENTS** | | Annual Financial Report | 20.1 |
| **III. MANAGEMENT REPORTS** | | Annual Financial Report | |
| **1. Information on the Company's activity** | | | |
| 1.1 | Overview of the activities (progress made and difficulties encountered) and earnings of the Company, each subsidiary and the Group | | 6.1 |
| 1.2 | Presentation of the ongoing business, earnings, financial situation and indebtedness of the Company and the Group | Annual Financial Report | 9.2<br>9.3.4<br>9.3.5 |
| 1.3 | Foreseeable development of the Company and/or the Group | | 12.1<br>12.2 |
| 1.4 | Key financial and non-financial indicators of the Company and the Group | Annual Financial Report | 3 |
| 1.5 | Subsequent events of the Company and the Group | | 20.2Appendix, 2 20.125) |
| 1.6 | Information on the use of financial instruments including the financial risks and risks in terms of pricing, credit, liquidity and cash facing the Company and the Group | | 20.124) |
| 1.7 | Main risks and uncertainties of the Company and of the Group | | 4 |
| 1.8 | Information on the Company's and Group's R&D | | 6.2<br>11 |

| Rubrics | | Information for | URD 2019 section |
|---|---|---|---|
| **2. Information on the Company's legal, financial and tax affairs** | | | |
| 2.1 | Choice of one of the two modes of general management of the Company in the event of a change | | 14.1 |
| 2.2 | Breakdown and changes in shareholding | | 18.1 |
| 2.3 | Names of controlled entities holding treasury shares and share of the capital they own | | 21.1.3 |
| 2.4 | Significant stakes acquired in companies headquartered in France during the period | | NA |
| 2.5 | Notice of holdings of more than 10% of the capital of another limited liability company; disposal of cross shareholdings | | NA |
| 2.6 | Company share buybacks and disposals | Annual Financial Report | 21.1.3 |
| 2.7 | Status of employee participation in the share capital | | 21.1.4 |
| 2.8 | Overview of information likely to have an impact in the event of a public offering: | Annual Financial Report | |
| | structure of the Company's issued capital; | | 21.1 |
| | statutory restrictions on the exercise of voting rights and the transfer of shares or contractual clauses brought to the Company's attention in application of Article L. 233-11 of the French Commercial Code; | | 18.3 |
| | direct or indirect stakes in the Company's share capital of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code; | | 18.3 |
| | list of holders of any securities conferring special rights of control and description of these rights; | | 18.1 |
| | control mechanisms provided in any employee shareholding scheme where rights of control are not exercised by the employees; | | 18.3 |
| | shareholder agreements the Company is aware of and which may impose restrictions on the transfer of shares and the exercise of voting rights; | | 18.4 |
| | rules applicable to the appointment and replacement of members of the Board of Directors or management board and to amendments to the Company's bylaws; | | 14.1.1 |
| | powers of the Board of Directors or management board, in particular the issuance and buyback of shares; | | 20.1 20.110.3) |
| | agreements entered into by the Company which are amended or terminated in the event of a change of control of the Company unless this disclosure (if not legally mandated) would seriously harm its interests; | | 18.5<br>18.6 |
| | agreements providing for indemnities for members of the Board of Directors or management board or employees if they resign or are dismissed without due cause or if their employment is terminated as a result of a public takeover offer. | | 15.1.1 |
| 2.9 | Summary table of the currently valid delegations to increase the share capital granted by the General Meeting | Annual Financial Report | 21.1.5 |
| 2.10 | Mention of any adjustments:<br><br>for securities giving access to the capital and stock options in the event of share buybacks;<br>for securities giving access to the capital in case of financial transactions. | | 21.1.4 |
| 2.11 | Amount of dividends distributed for the past three financial years | | 20.8 |
| 2.12 | Amount of non-tax deductible expenses and charges | | 20.2 |
| 2.13 | Terms of payment and breakdown of the balance on trade and customer payables by due date | | 20.2 |
| 2.14 | Injunctions or fines for anti-competitive practices | | N/A |
| 2.15 | Agreements between a corporate officer or shareholder holding more than 10% of voting rights and a subsidiary (excluding day-to-day agreements) | | 15.1 |
| 2.16 | Table of results for the past five financial years | | 20.1<br>20.2 |
| 2.17 | Statement of non-financial performance | | N/A |

| Rubrics | | Information for | URD 2019 section |
|---|---|---|---|
| **3. Information on corporate officers** | | | |
| 3.1 | List of all offices and positions held in any company by each corporate officer during the financial year | | 14.1.1<br>14.1.2 |
| 3.2 | Compensation and benefits in kind paid during the period to each corporate officer by the Company, entities it controls and the entity controlling it | | 15 |
| 3.3 | Agreements on taking up, terminating or changing positions | | 15.1.1 |
| 3.4 | If stock options are granted, mention of the information whereby the Board of Directors decided to:<br><br>either prevent executives from exercising their options for the duration of their term of office;<br>or require executives to hold all or part of the shares resulting from options already exercised in registered form for the duration of their term of office (specifying the percentage set). | | 15.1.1 |
| 3.5 | Summary of trading in the Company's shares by executives and related parties | | 15.3 |
| 3.6 | If bonus shares are granted, mention of the information whereby the Board of Directors decided to:<br><br>either prevent executives from selling their bonus shares for the duration of their term of office;<br>or set the number of these shares they must keep in registered form for the duration of their term of office (specifying the percentage set). | | 15.1.1 |
| **4. The Company's CSR information** | | | |
| 4.1 | Account of the consequences of the Company's activity on its employees and the environment and of its social commitments to sustainable development, combating discrimination and promoting diversity | | 8.3<br>8.4 |
| 4.2 | Information on dangerous activities | | |
| **IV. STATEMENT OF THE NATURAL PERSONS RESPONSIBLE FOR THE ANNUAL FINANCIAL REPORT** | | Annual Financial Report | 1.1<br>1.2 |
| **V. STATUTORY AUDITORS' REPORT ON THE COMPANY FINANCIAL STATEMENTS** | | Annual Financial Report | 20.5 |
| **VI. STATUTORY AUDITORS' REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS** | | Annual Financial Report | 20.5 |

# 26. GLOSSARY

**Histopathology**: technical, human and veterinary medical specialty, which focuses on the study of macroscopic and microscopic lesions in pathological tissues sampled from a living or dead subject;

**Autofluorescence**: light which is generated naturally by biological tissues, for example, under the action of illumination. Endoscopic imaging through autofluorescence therefore consists of analyzing this light in order to enhance, for instance, the detection of precancerous lesions;

**Biopsy**: mechanism that consists of taking a sample from the organism in order to carry out a microscopic examination;

**Optical biopsy**: see endomicroscopy;

**Bronchoscopy**: endoscopic examination enabling the visual exploration of the trachea and the bronchi and taking samples for analysis;

**Catheter**: medical device consisting of a tube designed to be inserted into the lumen of a body cavity or blood vessel, enabling drainage or infusion of liquids, or access for other medical devices;

**Cholangiocarcinoma**: biliary tract tumor;

**Colonoscopy**: specific case of endoscopy consisting of an exploratory examination of the colon (from the rectum to the small intestine);

**Cystoscopy (or endourology)**: an endoscopic medical examination used to examine the inner wall (mucosa) of the bladder via the urethra and possibly the ureters. This examination also enables therapeutic intervention;

**Dysplasia**: cellular/architectural modifications, the intensity of which defines the grade of dysplasia (Low grade = benign tumor, High grade = malignant tumor, in situ = not crossing the basal membrane);

**Echoendoscopy**: exploration of the tracheobronchial tree combining endoscopy and ultrasonography. It is used to identify and take biopsies of structures situated behind walls and not visible with conventional endoscopy (essentially nodes, tumors and cysts).

At the end of the bronchoscope, an ultrasound probe is used to capture images in mode B and Doppler;

**Distal tip**: The farthest tip of a mini-probe, for instance. The distal tip of the confocal mini-probes contains optical micro lenses;

**Endo-brachy esophagus (EBO or Barrett's Esophagus)**: complication of gastroesophageal reflux which, if it is not treated, can evolve into esophageal cancer;

**Endomicroscopy**: endoscopic procedure using a device which provides visualization of tissues at microscopic level;

**Endoscopic Confocal Microscopy via miniprobe (ECM)**: endomicroscopic procedure using a miniprobe which is compatible with standard endoscopes. The only ECM system available is the Cellvizio;

**White light endoscopy**: traditional endoscopy;

**EGD (Esophagogastroduodenoscopy)**: upper endoscopy used to examine the esophagus, stomach and duodenum;

**Multicenter clinical trials**: clinical trials that take place in several different places simultaneously;

**Randomized clinical study**: see "Randomized clinical trial";

**Randomized clinical trial**: Clinical trial of a new treatment during which participants are assigned at random to the control group or the experimental group;

**Histology**: a branch of biology and medicine that studies biological tissues;

**Narrow Band Imaging (NBI)**: NBI is a technology developed by Olympus based on an optical filter which can be used to improve visibility and contrast between capillaries, veins and other microstructures;

**Distal lesion**: lesions situated at the farthest tip of a given organ esophagus, biliary tract, etc.);

**Dysplastic lesion**: precancerous lesion;

**Barrett's Esophagus**: see Endo-brachy-esophagus (EBO);

**Metaplasia**: transformation of a cellular tissue. Reversible phenomenon not disturbing the tissue's functions;

**Advanced mosaic**: optimized treatment of a succession of adjacent images used to reconstruct wide field maps of a mucosa;

**Mucosectomy**: endoscopic treatment of a precancerous lesion consisting of a resection of the mucosa and possibly of the sub-mucosa in a hollow organ, such as the colon, esophagus or stomach;

**Confocal miniprobes:** invention of Mauna Kea Technologies. They are made up of a bundle of several tens of thousands of optical fibers sequentially scanned by a laser beam emitted by the scanning unit. They transport the Laser beam to the area to be observed, inside human anatomic tracts, through other standard endoscopic devices (colonoscope, gastroscope, bronchoscope, cholangioscope, etc.), a catheter or even a needle;

**Nodules**: abnormal, rounded, and palpable formations on or under the skin, which can be benign or malignant. Some nodules can be cancerous tumors;

**Optoelectronics**: combination of optical and optoelectronic technologies;

**Polyp**: growth of the mucosa (typically in the colon) that can be benign or malignant. Some polyps can be flat and very hard to detect;

**Resection**: surgical ablation of part of an organ or a pathological tissue such as a tumor;

**Transurethral resection**: this procedure takes place via the natural routes with no abdominal opening. The surgeon inserts a device called a resector into the urethral channel.

The operation takes place under visual control. The resector is used to remove the lesion and coagulate the various vessels which are likely to bleed. The tissues removed are sent to the laboratory for analysis. This procedure is used for both biopsies and the resection of bladder tumors;

**Learned Society**: society or organization formed by groups of experts who, through their work and discussion, ensure the progress of knowledge in their field of activity;

**Biliary and/or pancreatic duct strictures**: shrinkage of the natural ducts, whether pancreatic or biliary;

**System for spectroscopic interrogation of colorectal polyps**: optical technology used to investigate the nature of a polyp by analyzing the light backscattered by the polyp tissues;

**Tomography**: Imaging technique enabling a virtual cutting of the human body. The scanner is an example of a tomographic technique. Endomicroscopy is also a tomographic technique that makes virtual cuts of the tissues;

**Tract**: set of organs constituting a system (digestive tract, genital tract, etc.);

**Ureter**: the ureters are muscular channels which carry urine from the kidneys to the bladder. In adults, the ureters are generally 25 to 30 cm long;

**Transpleural route**: route of access across the pleura, i.e. the space between the lungs and the thoracic wall.

# 27. LIST OF CLINICAL PUBLICATIONS

Clinical publications are available on the Company's website using the following link:

http://www.maunakeatech.com/en/content/clinical-evidence